

**Intellectual Property Rights and the Campaign for Access to Essential
Medicines: The Advocacy Role Assumed by Médecins Sans Frontières**

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**Submitted in partial fulfillment
of the requirements for the degree of**

Master of Arts

**Faculty of Social Sciences, Brock University
St. Catharines, Ontario**

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Abstract

Non-governmental organizations and transnational networks have been increasingly successful at gaining influence within issue areas traditionally controlled by the state. In many instances, non-state actors have been instrumental in forcing issues onto the global agenda, have aided in the development or transformation of global regimes, and have participated in securing state compliance for the adoption of new international norms.

This paper argues that, consistent with social constructivist theory, ideas are important in influencing state preferences and change may be possible when certain factors are present. If non-state actors can influence states, it is meaningful to understand how this happens.

This paper focuses on a campaign led by Médecins Sans Frontières that began in the late 1990s to acquire affordable medicines for patients in developing states that could not afford patented drugs. The campaign reached a measure of success in that member states of the World Trade Organization re-negotiated contested terms and meanings within the trade agreement for intellectual property rights and allowed concessions that would benefit lower income states. What factors contributed to the success of the campaign? And what were the most important factors - the issue, the actors or the mechanisms used?

Acknowledgements

I would like to express gratitude to my thesis advisors, Hevina Dashwood and Dan Madar, for their valuable guidance throughout the research and writing process.

In addition, I am indebted to the faculty and staff that comprise the Department of Political Science at Brock. I benefited from their interest in my work, and in particular, from the ongoing encouragement offered by Ingrid Makus and Paul Hamilton, and also Bob Murray, currently at the University of Alberta.

List of Abbreviations

ACT UP	AIDS Coalition to Unleash Power
AIDS	acquired immune deficiency syndrome
ARV	anti-retroviral
AZT	azidothymidine
CP Tech	Consumer Project on Technology
d4T	stavudine
DNDi	Drugs for Neglected Diseases <i>initiative</i>
EU	European Union
GATT	General Agreement on Tariffs and Trade
GSP	Generalized System of Preferences
HAI	Health Action International
HIV	human immunodeficiency virus
ICESCR	International Covenant on the Economic, Social and Cultural Rights
ICRC	International Committee of the Red Cross
IMF	International Monetary Fund
IP	intellectual property
ITO	International Trade Organization
MDG	Millennium Development Goals
MSF	Médecins Sans Frontières
NGO	non-governmental organization
PEPFAR	President's Emergency Plan for AIDS Relief
TAC	Treatment Action Campaign
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development

UNHCHR	United Nations High Commission for Human Rights
UNICEF	United Nations Children's Fund
US	United States
USTR	United States Trade Representative
WHA	World Health Assembly
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WTO	World Trade Organization

Chapter 1

Non-governmental organizations and transnational networks have been increasingly successful at gaining influence within issue areas traditionally controlled by the state. In many instances, non-state actors have been instrumental in forcing issues onto the global agenda, have aided in the development or transformation of global regimes, and have participated in securing state compliance for the adoption of new international norms. Some of the most successful campaigns by advocacy groups that have resulted in the internalization of new norms at the global level have been those that resonate with a human rights framework or that deal with the environment.¹ This would suggest that state behavior may not be fixed and that other factors may influence their behavior at the international level.

This paper will focus on a campaign that began in the late 1990s to acquire reasonably priced pharmaceuticals for patients in developing states that could not afford patented brand name medicines. Led by non-governmental organizations, the campaign, it can be argued, reached a measure of success in that member states of the World Trade Organization (WTO) re-negotiated contested terms and meanings within the trade agreement for intellectual property rights and allowed new concessions that would benefit lower income states. If non-state actors can influence states, it is meaningful to understand how this happens. What factors contributed to the success of the campaign? And what were the most important factors - the issue, the actors or the mechanisms used?

One of the leaders of the campaign was a non-governmental organization, Médecins Sans Frontières (MSF). This paper will argue that MSF has been effective in impacting pharmaceutical access and the trade policy between states, and that there are several

¹ Margaret E. Keck and Kathryn Sikkink, *Activists beyond Borders: Advocacy Networks in International Politics* (US: Cornell University Press, 1998), 9, 26-28.

factors that make MSF unique as an organization contributing to its success in this issue-area. First, the simultaneous use of advocacy and confrontation has been embedded in the culture of MSF since its inception. Second, it is a transnational organization with offices and ongoing operational missions in a large number of states. This allowed MSF to reach a wide constituency and draw support quickly. Third, MSF has an excellent reputation as a leading humanitarian organization with expertise in health issues affecting developing states. MSF uses moral authority to make demands and draw attention to what it considers to be errant behavior. Fourth, MSF maintains a policy of independence from political and religious powers, and is financially supported primarily by the private sector. This has allowed MSF to pursue principled ideas without concern for its future funding. Fifth, MSF dedicated substantial resources to its Campaign for Access to Essential Medicines and formed an epistemic community to support it. The epistemic community was able to provide evidence-based research and had the credentials to gain access to policy-makers within international organizations and governments. Sixth, MSF has used the media and the internet effectively to mobilize public opinion, to contest actions and claims that are in opposition to its goals, and to provide education about the issue of pharmaceutical access. Seventh, MSF was a member of the access network, coalition and social movement and provided leadership throughout. The goals of the network and coalition were consistent with the goals of MSF and it was able to graft its agenda to the larger movement.

Finally, MSF used carefully crafted strategies to frame the access issue with lenses tailored to different stakeholders. MSF employed the framing of a basic human right to health and gained grassroots support by invoking norms rooted in social justice by

contrasting the wealth of transnational pharmaceutical corporations with the suffering of those dying because they could not afford essential medicines. Alternately, when dealing with international organizations and wealthy governments, MSF reinforced the sovereign right of governments to provide for their populations, and advocated that governments, particularly in lesser developed states, be allowed to take necessary measures to protect public health.

Organization of the Paper

In this chapter, I will provide a brief overview of the issue concerning intellectual property rights and pharmaceuticals access. This is followed by a review of the literature that theorizes the behavior of states and the role of non-state actors in international politics, and a discussion to determine how the arguments in this paper are situated within the literature. In the second chapter, I will review the history of intellectual property rights and how IP rights became entrenched in international trade rules. This includes a discussion of certain rules contained in the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) under the WTO and the problems that arose specifically in the area of pharmaceuticals. The positions argued by both the corporate coalition and the transnational access coalition will be examined, as will the modifications made to the TRIPS Agreement.

The third chapter is structured to provide the historical context for the formation of MSF and to discuss the assumptions that underpin its conception of humanitarian action. This is followed by an overview of the changing nature of global health in the 1980s and 1990s and by an explanation of the link between MSF and the pharmaceutical issue. I

will examine the focus and actions of the Campaign for Access to Essential Medicines, its partnering and strategies, and MSF's continuing commitment to the issue.

The fourth chapter will provide an analysis of the access campaign and strategies used by MSF to frame the issue and influence state behavior, and I will examine some of the outcomes to determine their implications for theorizing in international relations. In addition, I will consider alternate explanations for shifts in state behavior and compliance with new norms for pharmaceutical access. Finally, I will conclude with suggestions about which factors might be most important for successful campaigns and propose areas for further research.

Research Methodology

This paper uses a case study approach to determine the factors that contributed to establishing and re-assessing the multilateral TRIPS Agreement and the impact of actions taken by MSF and other actors to alleviate the barriers for accessing essential medicines. The case study approach is a contextual examination of a phenomenon used for explaining or theorizing about an aspect of an event through inferential reasoning.² Case studies are useful for studying in rich and intricate detail decision-making processes of an individual or organization, tipping points affecting outcomes, and social factors including discourse and identity for both exploratory and explanatory investigations.³ By incorporating process-tracing, a method that attempts to link "possible causes with observed outcomes,"⁴ the researcher relies on multiple sources of material to understand

² Alexander L. George and Andrew Bennett, *Case Studies and Theory Development in the Social Sciences* (Massachusetts: MIT Press, 2005), 17-18.

³ Ibid. 9-10.

⁴ Ibid., 6.

complexity in sequences and actions. Process-tracing can therefore help to mitigate some of the pitfalls of the case study method including case selection bias, over- or understatement of linkages and estimating the relevance of accumulated data.⁵

By analyzing the role of MSF through the case study method, the paper will also consider the existing theories in international relations and determine which theories can best explain the processes and outcomes of the campaign. It will be shown that a constructivist approach offers a more complete explanation.

The research materials for this paper include sources such as books and peer-reviewed journals, as well as websites maintained by some of the main actors in the study. In addition, I have employed content analysis of the web-based 'listserv' hosted by Consumer Project on Technology (CP Tech) during the early years of the campaign, archived web pages and websites maintained by various non-state actors including non-governmental and international organizations. Triangulation of some information was mandatory to sort through conflicting reports for dates and sequencing, statistics, and actions attributed to various actors.

Some of this research was generated from ideas and information from two conferences I attended at the University of Toronto: "Global Health Research," May 2004,⁶ and IDEA & UAEM's "Universities, Innovation and Global Medicine Access," April 2009.⁷ I

⁵ Ibid., 22-27.

⁶ The idea for this research project was stimulated by attending the 2nd Annual Global Health Research Conference, "Mobilizing Research to Action: A Canadian Contribution," May 14-15, 2004 at the Centre for International Health, Faculty of Medicine, University of Toronto. Stephen Lewis gave the opening address which focused on the numbers of orphans from neglected diseases in Africa and MSF maintained an extensive poster display decrying the lack of medicines for neglected diseases. The posters were highly effective; they drew much attention from conference attendees and elicited the emotive response which they were designed to do. On a personal note, I gathered up their offered materials and embarked on this research quest.

⁷ The Initiative for Drug Equity and Access is at the Leslie Dan Faculty of Pharmacy, University of Toronto, and Universities Allied for Essential Medicines is a student-based organization with chapters

also gained insight into the broader issue at seminars sponsored by the Comparative Program on Health and Society at the Munk Centre including a panel on “Canada’s Reform of IP Law,” December 2004, and several featuring the research of Post-Doctoral Fellow, Lisa Forman, which were particularly informative for my work.

Overview of the Global Access to Medicines Regime

For more than a decade, the relationship between intellectual property rights and the ability to access necessary medicines has been a concern for states and non-governmental organizations involved in health policy. The catalyst for the debate on the issue was twofold: the invention of anti-retroviral medicines that could potentially treat and prevent the spiraling number of infections and deaths related to HIV/AIDS in developing countries, and the formation of the World Trade Organization, an international organization formed to standardize and enforce trade laws between states.

Although the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) were first recognized in 1981, the rapid spread of the related diseases was most notable in the 1990s. By 2001, UNAIDS and the World Health Organization estimated that 40 million persons globally were living with HIV/AIDS and approximately 20 million had already died from AIDS-related illnesses making the virus the fourth leading cause of death.⁸ The spread of the virus was most prevalent in developing

across the United States and Canada. Both are committed to promoting equitable access to inventions stemming from technology and molecule discoveries that originate in University laboratories. More about UAEM is available from their website at <http://essentialmedicine.org/>

⁸ UNAIDS/WHO, “AIDS epidemic update,” December 2001, 1.

<http://www.who.int/hiv/facts/en/isbn9291731323.pdf> (accessed May 1, 2010). It should be noted here that many statistics are truly estimates. Reporting systems for HIV/AIDS were poor or non-existent in most developing states due to a lack of health infrastructure and because of the stigma of self-reporting or seeking treatment, particularly in the early years. Reporting problems are well-documented in the document, WHO, Regional Office for Africa, “HIV Surveillance Report for Africa 2000,” November 2001,

countries,⁹ particularly in those located in sub-Saharan Africa which accounted for 28 million cases (70% globally) of those living with HIV, and the incidence of new infections and deaths was rising annually.¹⁰

Because the virus was affecting a large proportion of the population in sub-Saharan Africa at the height of their working and childbearing years,¹¹ multiple social and economic problems arose, including reduced productivity in the industrialized and agricultural sectors, plummeting life expectancy¹² and increased individual poverty. In poor countries, public health resources were underfunded or not accessible for a variety of reasons, including the introduction of user fees and privatization under structural adjustment programs, insufficient numbers of health care providers, and the lack of facilities in rural settings.¹³ Personal assets frequently had to be sold to pay for medicines, medical care and for burials; children were often withdrawn from education systems to care for the ill or to provide an alternate income to buy basic needs such as food.¹⁴

http://data.unaids.org/Publications/External-Documents/hiv%20surv%20rpt%202000_en_pdf.pdf (accessed May 1, 2010).

⁹ For the purpose of this paper, the term “developing countries” includes low and middle income states as defined by the World Bank based on Gross National Product. The 2009 figures per capita cite low income as \$995 or less (includes 49 states: 33 located in Africa, 15 in Asia, plus Haiti), lower middle income as \$996 - \$3945 and upper middle income as \$3946 - \$12195. High income is currently defined as having a GNP per capita of at least \$12,196. See World Bank, “Data: How We Classify,”

<http://data.worldbank.org/about/country-classifications> (accessed November 20, 2010).

¹⁰ UNAIDS/WHO, “AIDS epidemic,” 2-3. In 2001, it was estimated that there was about 5 million new infections and 3 million deaths globally, with 3.4 and 2.3 million respectively occurring in Africa.

¹¹ WHO, “HIV Surveillance,” 17. Peak age for males was reported to be 30-34, and females to be 25-29.

¹² UNAIDS/WHO, “AIDS epidemic,” 8-9. Life expectancy for Botswana, Malawi, Mozambique and Swaziland had dropped from about 62 years to less than 40, while South Africa dropped from 67 to 47 years from 1990-2000.

¹³ Ross P. Buckley and Jonathan Baker, “IMF Policies and Health in Sub-Saharan Africa,” in *Global Health Governance: Crisis, Institutions and Political Economy*, ed. Adrian Kay and Owain David Williams (UK: Palgrave Macmillan, 2009), 214-215.

¹⁴ UNAIDS/WHO, “AIDS epidemic,” 7.

In Africa, where the virus affected men and women equally, mother-to-child transmissions of HIV were increasing and in some countries such as Botswana and Zimbabwe, antenatal clinics had reported that a third of the pregnant women tested were HIV positive.¹⁵ In addition, with an accumulated 16.4 million HIV-related deaths having occurred in the sub-Saharan region, it was estimated that more than 12 million children had already been orphaned.¹⁶

The first drug to combat HIV, Retrovir or AZT, was produced by Glaxo-SmithKline in 1987, but it was not until 1996 when protease inhibitors used in combination with AZT were introduced that HIV/AIDS became viewed as a potentially manageable illness. However, new international trade rules had been recently institutionalized and protected the originator drug companies from unauthorized use of their invention under patent laws.

Embedded in the WTO package of trade rules was the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). When the TRIPS Agreement took effect in 1995, patent laws that were previously enshrined in a patchwork of non-binding treaties became harmonized and enforceable for both the invention of products and processes. In the case of pharmaceuticals, the originator's rights were protected for twenty years under patent, and this soon became perceived as a barrier for the access of affordable essential drugs in lower income states.

Because the TRIPS Agreement was to be phased in over five years, pharmaceutical companies in some developing states could continue to manufacture certain drugs until 2000 when all states were to be "TRIPS" compliant. Some drug patents would also

¹⁵ WHO. "HIV Surveillance," 13.

¹⁶ Ibid., 17.

expire during that period allowing for ongoing production. However, the terms of this limited production did not allow for the newer discoveries of anti-retroviral (ARV) medicines. Under patent, the ARV drugs that appeared in the late 1990s would command a very high price and would remain outside the financial reach of countries whose populations were most profoundly affected by the HIV virus.

For several years leading up to the negotiations, the U.S. had strengthened its own laws at the behest of transnational corporations who invested heavily in research and development in high technology and knowledge-intensive industries. Corporations were anxious to protect their investments from 'free-riders', manufacturers in newly industrializing states that could realize profits by producing inexpensive copies of goods without bearing the burden of development costs. Unable to reach their objectives through the World Intellectual Property Organization (WIPO), representatives of the most affected industries had convinced the U.S. government that intellectual property rights were trade issues and should be included in the Uruguay Round of trade negotiations.

Although there was resistance to the TRIPS Agreement from developing countries, the benefits of the new trade package outweighed the disadvantages, and opposition was ineffectual. In addition, the potential consequences of an entrenched intellectual property rights regime went largely unnoticed by most non-governmental organizations who, during the years leading up to "TRIPS", were immersed in emergency assistance and reconstruction work in the wake of the growing number of civil conflicts.

The TRIPS Agreement was in force for more than 18 months when Health Action International, a transnational network, convened the first conference for non-

governmental organizations to discuss the implications of the TRIPS Agreement on health issues. This set in motion a series of conferences that focused on access to essential medicines and included non-governmental organizations, international organizations, health officials from states, and representatives from the pharmaceutical industry. Through the conferences, a transnational advocacy coalition formed that would pursue access to affordable drugs for patients in developing states.

The debate surrounding the impact that intellectual property rights had on the access to pharmaceuticals was divided into two opposing arguments. Wealthier states and transnational pharmaceutical corporations claimed that patents were necessary to protect and reward innovation and to facilitate future research and development. The corporate group insisted that patents were not relevant to the problem of access in lower income states and frequently identified poverty and lack of infrastructure as the primary barriers. In addition, they viewed the use of compulsory licensing and parallel importing permitted under the TRIPS Agreement to be invalid.

The opposing side, the access coalition, was comprised mainly of non-governmental health and human rights organizations, developing states, and generic drug manufacturers who argued that patents were responsible for keeping drug prices high and prevented access to less expensive generics. They challenged the correlation between patents and profits for research and development, and claimed that in spite of other barriers, lives could be saved if medicines were accessible. Finally, they advocated that states had a right to protect public health by using the flexibilities permitted within the TRIPS Agreement.

A crucial point in the debate was when South Africa attempted to enact its *Medicines and Related Substances Control Amendment Act, 1997* and was challenged in court by the Pharmaceutical Manufacturers Association and the drug companies it represented. The suit was supported by the U.S. and the European Union who tried to coerce South Africa into withdrawing its legislation. This gave the Access coalition a platform on which to mobilize civil society on a global scale, taking the form of a transnational social movement. Under intense pressure, the U.S. and E.U. withdrew their support of the lawsuit and eventually the legal challenge was withdrawn by the drug companies. The African Group of states asked the “TRIPS” Council to clarify the use of compulsory licensing and parallel importing, and this led to the *Doha Declaration on the TRIPS Agreement and Public Health* in 2001 supporting the right to protect public health and use the flexibilities outlined in “TRIPS”.

Early in the campaign, Médecins Sans Frontières assumed one of the leading roles for the transnational access coalition. As an emergency medical agency, MSF worked in many of the countries with the largest populations suffering from HIV/AIDS and other neglected diseases. They had a practical understanding that access to medicines was severely limited in lower income countries and had an interest in overcoming the barriers that prevented treatment for their patients.

MSF was awarded the Nobel Peace Prize in 1999 and made a commitment to the pharmaceutical issue by formalizing their Campaign for Access to Essential Medicines. The main actors from MSF who piloted the Access Campaign were professionals in the fields of medicine, pharmaceuticals and trade law. Supported by MSF’s team of

researchers and experts in the field they constituted an epistemic community¹⁷ which strengthened their ability to contest opposing claims and influence pharmaceutical policy through multiple access points. In addition, MSF was able to graft its agenda to that of the larger coalition and social movement to promote access to drugs for several diseases other than HIV/AIDS. MSF collaborated with various actors which led to lower drug prices and access to generics, and they published comparative selling prices for patented and generic drugs to increase leverage. MSF engaged in clinical trials, provided technical assistance to governments, and worked with intergovernmental organizations to promote access. Through the effective use of media and internet, MSF sustained pressure on pharmaceutical corporations and governments and mobilized civil society through several online petitions to oppose policies. Finally, the MSF campaign has continued to collaborate with multiple stakeholders to seek out innovative ideas to stimulate research and development for neglected diseases, and to push for access to the newer second and third line treatments.

Theoretical Approaches for the Study of International Relations

In order to examine the impact that non-state actors have on state behaviour, this paper relies on analytical premises that are typically associated with a constructivist framework found within liberal theories of international relations. Unlike traditional realist and neoliberal theories, liberalism opens a space for the examination of domestic politics and non-state actors to consider their influence on state preferences. A core assumption is

¹⁷ An epistemic community is defined by Peter Haas as “a network of professionals with recognized expertise and competence in a particular domain or issue area.” Peter M. Haas, “Introduction: epistemic communities and international policy coordination,” *International Organization* 46, no.1 (Winter 1992), 3.

that state identity and interests are formed as a result of domestic political structures or processes, and these in turn inform state preferences and actions at the international level.

Traditional theories of international relations are less suitable for this paper and its emphasis on the impact of non-state actors because they perceive states as the only valid unit of analysis, and assume that state behaviour is the result of rational self-interest. The discussion will begin with a review of the primary assumptions that underpin traditional theory to establish the deficiencies that constructivist approaches can better address.

Realism and Neorealism

Primarily founded on the structural distribution of capabilities, classical realist theory has concentrated on the balance of power between states at the international level. The perpetual pursuit of power is understood to be inherent in human activity as a means to pursue specific interests.

Classical theorists, such as E.H. Carr and Hans Morgenthau, have argued that at the international level states pursue their interests and that order is maintained through a balanced but ongoing struggle for power. State interests are not assumed to be necessarily similar to, nor in harmony with, the interests of other states and may change due to the effects of time and place. In the absence of universal moral principles to guide state actions, military and other material capabilities are considered to be the key element in this systems-level approach that perceives states as rational actors competitively seeking means to sustain or increase power.¹⁸

¹⁸ Hans Morgenthau and Kenneth W. Thompson, *Politics Among Nations: the Struggle for Power and Peace*, 6th edition (New York: McGraw-Hill, 2006): 4-13. See also E.H. Carr, *The Twenty Years' Crisis, 1919-1939* (New York: Palgrave, 2001), particularly chapters 3 and 4 for the rationale underlying the realist assumptions.

Neorealism, or structural realism, arose from the debate about why states seek power and re-conceptualizes the pursuit of power as a means to ensure their existence. Although neorealists such as John Mearsheimer, Stephen Walt and Kenneth Waltz disagree about how much power is desirable, they reject the classical view that the pursuit of power is a result of human nature. Rather, neorealism concentrates on the structure of the international system to explain state behaviour and maintains that states are rational unitary actors existing in anarchy, which drives them to act in similar ways to ensure their own survival.¹⁹ Without the benefit of a central overarching authority, and because states cannot predict how other states will behave in the future, the concept of self-help must be adopted. To survive, states will protect their interests and therefore their actions would be expected to reinforce sovereignty and security. The main political tool is the threat or use of force.²⁰

Empowerment of the state and security are based on material factors - not just militarily, but also through generating wealth economically, technologically and territorially.²¹ Neo-realists argue that the accumulation of wealth is viewed as a zero-sum competition between states so that each seeks relative gains. For this reason, states are threatened by actions that could diminish the advantages they maintain over others. This also makes it difficult for states to develop mutual trust and co-operate.²²

¹⁹ Kenneth N. Waltz, *Theory of International Politics* (US: Addison-Wesley Publishing Company, 1979), 91-96. As a defensive realist, Waltz warns against the pursuit of hegemonic power, whereas offensive realists argue that strategically states should pursue as much power as possible. See J.J. Mearsheimer, *The Tragedy of Great Power Politics* (New York: Norton, 2001) for a discussion of offensive realism.

²⁰ John J. Mearsheimer, "Structural Realism," in *International Relations Theories: Discipline and Diversity*, ed. Tim Dunne, Milja Kurki and Steve Smith (UK: Oxford University Press, 2007), 72-74.

²¹ Ibid., 72-73. Mearsheimer refers to this as latent power.

²² Ibid., 72-75.

In this case study, realist theory may explain why powerful states dominated the Uruguay Round of negotiations and insisted on stringent intellectual property rights to protect their economic position and advanced level of technology. Realists would expect powerful states to continue to protect their major industries including lucrative transnational pharmaceutical corporations in order to benefit from their technical knowledge and financial investment. Therefore, realism cannot adequately address why, under pressure, powerful states appeared to change their preferences, weakening the TRIPS Agreement to accommodate health concerns exclusive to developing states. Nor does realism explain why major states backed down from supporting or pursuing legal challenges in the case of South Africa and Brazil when faced with rising opposition from non-state actors advocating for the access to medicines for developing states.

Liberalism

Based on the Kantian philosophy of peace, liberal theories accept that states are formed with the consent of citizens and that ideational factors affect how states are individually constructed. While cooperation between states in areas such as collective security and economic interdependence may be evidence of a common desire to avoid conflict, differences in state interests and identities persist, and a variety of liberal theories have devolved that focus on how state interests and identities are formed and transformed and consider which variables are important in the formation.²³

Liberalism continues to view states as primary rational actors at the international level although state preferences and identities are understood as being constituted by their domestic politics. State structures and policy are assumed to be formed from the 'bottom

²³ Diana Panke and Thomas Risse, "Liberalism" in *International Relations Theories: Discipline and Diversity*, ed. Tim Dunne, Milja Kurki and Steve Smith (UK: Oxford University Press, 2007), 90-93.

up' as a cumulative reflection of the demands from a rational and risk-averse polity.²⁴ Consequently state preferences and identity may be transformed due to social factors such as re-distribution of resources or political power, or because of changing ideas and beliefs. State officials are considered to be constrained in their policy choices by competing demands from within the state and by pressures exerted from outside.²⁵

At the international level, states are also seen as being subject to constraints imposed by the costs of pursuing interests in the global arena. States are not assumed to be innately in conflict, although conflict is more likely to occur when the interests pursued and strategies employed in a specific policy area constrain or threaten the preferences and strategies of other states.²⁶

Liberal approaches tend to be based on the particularities of either structure or agency. Those that emphasize structure as a defining factor may examine how domestic features including political and economic institutions shape state preferences, whereas those that focus on agency may consider the interests and identities of relevant actors and groups within a society, including corporations and civil society organizations, as more important in the construction of policies that guide state actions.²⁷

Neoliberal Institutionalism

Neoliberals such as Robert Keohane and Joseph Nye argue that cooperation between states is not only possible, but is frequently desirable when benefits can be shared and mutual (absolute) gains realized. However, because anarchy exists, collective-action problems will arise given that states need to self-regulate compliance with international

²⁴ Andrew Moravcsik, "Taking Preferences Seriously: A Liberal Theory of International Politics," *International Organization* 51 no.4 (Autumn 1997): 516-517.

²⁵ *Ibid.*, 516-517.

²⁶ *Ibid.*, 517-521.

²⁷ Panke and Risse, 92-93.

agreements. States in this model are considered to be rational actors that pursue their interests based on a cost-benefit analysis, although preferences and immediacy of returns may vary. Because there are incentives to defect or deviate from agreements in order to maximize individual gains, states cannot know how others will react, and therefore international regimes may be adopted to cope with the problems associated with cooperation.²⁸

International regimes are defined by Stephen Krasner as “principles, norms, rules, and decision making procedures around which actor expectations converge in a given issue-area,”²⁹ and can be designed as formal or informal arrangements between states to facilitate sustained cooperation. Regimes may seek to standardize expectations in a defined area such as trade by defining the scope of the agreement, enumerating the rules of behavior, monitoring compliance, and regulating sanctions that can be used against defectors.

Some regimes may be managed by forming international organizations, defined as “multi-level linkages, norms and institutions.”³⁰ They may be created to minimize the transaction costs of cooperation by providing a forum where states can negotiate for similar understandings of the terms of cooperation, facilitate ease of monitoring other states’ compliance with the terms of agreements, and offer a transparent adjudication mechanism.³¹

²⁸ Lisa L. Martin, “Neoliberalism,” in *International Relations Theories: Discipline and Diversity*, ed. Tim Dunne, Milja Kurki and Steve Smith (UK: Oxford University Press, 2007), 111-112.

²⁹ Stephen D. Krasner, “Structural causes and regime consequences: regimes as intervening variables,” *International Organization* 36, no.2 (Spring 1982): 185.

³⁰ Robert O. Keohane and Joseph S. Nye, *Power and Interdependence*, 3rd ed. (US: Longman, 2001), 47.

³¹ Martin, 111-112.

The neoliberal view of state behavior within international organizations is conceptualized as a structural approach, where states are the principals and the organization provides an agency function for member states. However, marked differences exist between international organizations, and some potential problems are worth noting. First, the discretionary powers of international organizations are varied, and their degree of autonomy may be strategically linked to the preferences of powerful states.³² Second, although international organizations tend to be rule-based, there is evidence that political bargaining frequently results in outcomes that reflect the preferences of the more powerful states. Evidence also shows that even at the WTO where enforcement mechanisms are not related to state power, the threat of future action is generally effective in producing outcomes that favour the more powerful.³³ Third, regime compliance may require adjustments that cannot be uniformly achieved without concessions or assistance, which produces the problem of moral hazard, and conditions are often placed on recipient states to compel them to meet their obligations.³⁴

In this case study, neoliberal theory can account for why states supported the structural framework of the World Trade Organization and may explain why states would agree to be constrained to the extent that benefits outweighed the costs of membership. However, the explanation for why the US withdrew its case against Brazil at the WTO's Dispute Body, and why the more powerful states would make concessions under the "TRIPS" regime for resource-poor states to access pharmaceuticals remains problematic within neoliberal thought.

³² Ibid., 119-120. The example cited by the authors relates to the World Bank's environmental policy as closely mirroring that of the U.S., however, it could be argued that the same principle is present in the World Trade Organization.

³³ Ibid., 115-117.

³⁴ Ibid., 118-119.

The approaches used in theories of realism, neorealism and neoliberal institutionalism concentrate on states as the primary unit of analysis and draw on rationalist assumptions to explain or predict state behaviour. The next section will examine some theoretical concepts that consider the role of non-state actors in international relations.

Approaches for the Study of Non-State Actors in International Relations

Attention to the role played by non-state actors at the international level can be traced back to observations that transnational relations in the 1970s were not limited to military considerations but were increasingly embedded in arrangements involving international trade and economics. Theorists such as Keohane and Nye challenged the claim that states were the only important actors at the international level, arguing that cooperation between states and growing interdependence had changed the concept of power beyond the military to include political and economic power.³⁵ There was an increasing number of multilateral instruments and institutions that provided rules and regulatory frameworks for states and other transnational actors in issue-areas such as the environment, trade and monetary policy, and the activities of transnational corporations.³⁶

The Role of Corporations in International Relations Theory

Initial studies that examined the role of non-state actors focused on corporations, which are sometimes referred to as the second sector: private non-state actors that wield an abundance of economic rather than political power. As industrialized states moved away from the model of the welfare state that was popular after World War II and instead

³⁵ Keohane and Nye, 9-10. The authors refer to this dynamic as 'complex interdependence.'

³⁶ Ibid., 17.

adopted classical economic theories³⁷ of markets unencumbered by government participation and regulation, corporations were presented with increased opportunities to expand both within and outside the home state.³⁸

Domestically, as states implemented neoliberal economic policies³⁹ there was a movement toward a more limited role for government in the supply of goods and services, and the separation of responsibilities between the public and private spheres became more pronounced.⁴⁰ Business interests based mainly on maximizing profits filled the void left by states, yet theorists studying non-state actors noted that the rise in private authority was mostly considered to be legitimate through the consent of the people.⁴¹

At the international level, the rise of transnational corporations was encouraged by the liberalization of national markets and trade policies, rising competition between firms, and the reduction of barriers previously attributed to borders, means of transportation and movement of capital. Rapidly evolving technologies and modes of communication in particular facilitated the flow of capital for foreign direct investment.⁴²

In response to claims that transnational corporations were gaining too much power and driving economic globalization, theorists such as Robert Gilpin and Susan Strange examined the relationship between markets and states and the role of transnational corporations on the changing nature of the state. From a state-centric viewpoint, Gilpin

³⁷ Notable classical theorists include Adam Smith ("invisible hand" of the market) and David Ricardo (comparative advantage), and more recently Friedrich Hayek and Milton Friedman.

³⁸ Virginia Haufler, "Global Governance and the Private Sector," in *Global Corporate Power*, ed. Christopher May (US: Lynn Reinner Publishers, 2006), 89-90.

³⁹ Neoliberal economic policy is based on classical liberal theories of IPE. See David N. Balaam and Michael Veseth, *Introduction to International Political Economy*, 4th edition, Chapter 3 (US: Pearson, 2008), 37-61.

⁴⁰ Haufler, 89.

⁴¹ Rodney Bruce Hall and Thomas J. Biersteker, *The Emergence of Private Authority in Global Governance* (Cambridge: Cambridge University Press, 2002), 4-5.

⁴² Balaam and Veseth, 367-368.

argued that states have remained the primary actors that establish the rules that corporations must follow and since the rules reflect the domestic interests of the most powerful states, these along with market forces influence economic outcomes.⁴³ According to Gilpin, “the extent and impact of globalization are greatly overstated” and that it is a movement consented to by governments that is prevalent only in North America, Western Europe and Pacific Asia.⁴⁴

Strange acknowledged that structural power can influence market behaviour but because markets are impersonal and reflexive, outcomes sometimes may have unintended consequences such as a reduction in state authority in specific areas.⁴⁵ She argued that states had lost some of their prior exclusivity and increasingly had to cooperate, coordinate or share policy decision-making with non-state actors.⁴⁶

Rather than recognizing transnational corporations as a threat to state power, states that adopt neoliberal economic policies generally regard corporations as agents for the re-allocation of resources and as a vehicle to correct inefficiencies in the global market.⁴⁷ However, the relationship between states and corporations can be both harmonious and contentious as each tries to maximize returns while gaining an advantage over competing states and businesses. States benefit from the ability of businesses to generate and invest financial wealth, invent and disseminate new technologies, provide employment

⁴³ Robert Gilpin, *Global Political Economy: Understanding the International Economic Order* (US: Princeton University Press, 2001), 18-23.

⁴⁴ *Ibid.*, 294 & 364.

⁴⁵ Susan Strange, *The Retreat of the State: The diffusion of power in the world economy* (Cambridge: Cambridge University Press, 1996), 29. It is interesting to note that Strange examined ten issues that she identified as the traditional purview of the state and concluded that only two areas had not been overly compromised: providing a social safety net for those who could not compete and building infrastructure to further support the market. See 73-82.

⁴⁶ *Ibid.*, 73.

⁴⁷ Rhys Jenkins, “Theoretical Perspectives on the Transnational Corporation,” in *International Political Economy: State-Market Relations in a Changing Global Order, 2nd Edition*, ed. C. Roe Goddard, Patrick Cronin and Kishore C. Dash (US: Lynne Rienner Publishers, 2003), 416-417.

opportunities, and develop natural resources.⁴⁸ In addition, states require the tax revenue generated by business activities to implement their own policies.⁴⁹ Similarly, transnational corporations depend on states for access to markets, labour and natural resources, and legal frameworks to support production and investment.

At the international level, corporate goals may depend on the cooperation of several states. The removal of trade barriers has required states to create new frameworks for regulatory or voluntary compliance in areas such as biosafety and environmental sustainability.⁵⁰ For other areas, such as intellectual property rights, corporate alliances have lobbied and convinced powerful states to institutionalize new international rules.⁵¹

Corporate power tends to vary between sectors and can be a result of industry specific command of resources, capital, or specialized technologies. Larger firms that appear highly mobile may be able to use this as leverage for gaining favourable policies from home states. The power of business can also be enhanced both domestically and globally through industry associations and effective lobbying tactics, particularly when political processes are open at multiple access points and interests can be aligned.⁵² Finally, because of the specialized knowledge some firms hold, they may be directly involved in the formulation of state policy in an advisory or research capacity, and may be able “to contest, dilute, and shape the detail”⁵³ of international obligations.

⁴⁸ A. Claire Cutler, Virginia Haufler and Tony Porter, “Private Authority and International Affairs,” in *Private Authority and International Affairs*, ed. A. Claire Cutler, Virginia Haufler and Tony Porter (NY: State University of New York Press, 1999), 5-6.

⁴⁹ Peter Newell and David Levy, “The Political Economy of the Firm in Global Environmental Governance,” in *Global Corporate Power*, ed. Christopher May (US: Lynne Rienner Publishers, 2006), 161.

⁵⁰ *Ibid.*, 162-163.

⁵¹ Haufler, 91.

⁵² Newell and Levy, 163-164.

⁵³ *Ibid.*, 164.

Theorists studying the features affecting the management of health at the global level have noted that the liberalization of the market has broadened consumer access to different products and services, increased competition between providers and manufacturers, and facilitated the shift of health services from the public sphere to the private domain.⁵⁴ However, the benefits and outcomes have been uneven.

Alan Ingram argues from a structuralist approach that the legacies of colonialism, structural adjustment policies, and the Cold War have contributed to the underlying burden of disease in poor countries and the inadequate response by governments to health crises.⁵⁵ International organizations, particularly the Bretton Woods institutions, are viewed as constraining policy choices that national governments could adopt for health because their programs continue to link state spending and poverty reduction to the funding and loans available through the World Bank and the International Monetary Fund (IMF).⁵⁶

It is also noted that the commodification of health produces externalities; for example, the absence of public control over the allocation of health resources can create greater inequities for access between rich and poor individuals within a state and between states in the North and South.⁵⁷ A cogent example of this lies in the access to antiretroviral

⁵⁴ Adrian Kay and Owain David Williams, "Introduction: The International Political Economy of Global Health Governance," in *Global Health Governance: Crisis, Institutions and Political Economy*, ed. Adrian Kay and Owain David Williams (UK: Palgrave Macmillan, 2009), 7-11.

⁵⁵ Alan Ingram, "The International Political Economy of Global Responses to HIV/AIDS," in *Global Health Governance: Crisis, Institutions and Political Economy*, ed. Adrian Kay and Owain David Williams (UK: Palgrave Macmillan, 2009), 84-86.

⁵⁶ Kay and Williams, 13-14. Ingram, 91

⁵⁷ Kay and Williams, 6, 11. The authors note that inequities can arise within states due to liberal policies, and as evidence, point to the US where 50 million people have no health insurance to ensure access.

treatment; while widely available in states of the North, it is estimated that in 2004, only 2% of those in need living in Sub-Saharan Africa were receiving treatment.⁵⁸

Theories that examine the role of the corporation add to the explanation for why powerful states and large pharmaceutical corporations desired strengthened trade regimes and how industry can influence the political process. Although pharmaceutical corporations incur substantial costs throughout the production cycle for the development of new drugs, they are among the most profitable in the business sector. During the period 1995-2002, they were ranked first in the United States, falling to fourth place after 2003.⁵⁹ By 2002, global drug sales were estimated to be US\$430 billion; half of the top twenty pharmaceutical corporations had their headquarters in the United States, while the remaining ten were scattered in Germany, Switzerland, France, Britain and Japan.⁶⁰ The considerable investment made by the companies in research and development, product promotion, and human resources directly benefited the domestic economies of the home state and the host countries of their subsidiaries. A strong patent regime protecting both product and process was an important factor for retaining profits and continuing investment in research and development.

Industry associations were also particularly strong in this case. The major U.S. pharmaceutical corporations Merck and Pfizer joined forces with entertainment and software representatives to form the Intellectual Property Committee that lobbied U.S.

⁵⁸ Ingram, 81.

⁵⁹ World Health Organization, *Public health, innovation and intellectual property rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, 2006, 18, <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> (accessed April 18, 2009).

⁶⁰ L.J. Sellers, ed., "Special Report: Fourth Annual Pharm Exec 50," *Pharmaceutical Executive* (May 2003), 42-52' <http://pharmexec.findpharma.com/pharmexec/data/articlestandard//pharmexec/182003/55215/article.pdf> (accessed July 20, 2010).

Congress to increase protections.⁶¹ Simultaneously, Merck and Pfizer were members of the Pharmaceutical Research and Manufacturers Association, which added pressure and also persuaded their counterpart organizations in Europe and Japan to launch similar appeals.⁶² Through careful framing, they were successful in aligning their interests with those of powerful states for the creation of the TRIPS Agreement.

Yet, as this case will demonstrate, corporate power and the pursuit of purely economic interests are not always the dominant considerations informing state behaviour at the international level. In spite of strong opposition and seemingly persuasive arguments from pharmaceutical corporations, states affirmed the right to protect health and to use measures contained in the TRIPS Agreement, and made concessions that would assist resource-poor states in obtaining less expensive medicines. Some states further responded to the revised rules for “TRIPS” by making significant domestic regulatory provisions to allow for the export of generic medicines under compulsory licensing to less developed states, although no economic gain would be realized.

Rather than being swayed by economic interests, states in this case study appear to be more responsive to the position rendered by the access coalition including a commitment to health and to the moral principles of social justice that medicines were possible and human suffering was needless. This would seem to be consistent with constructivist claims that states are concerned about identity and human rights concerns.

⁶¹ Susan K. Sell, *Private Power, Public Law* (UK: Cambridge University Press, 2003), 2, [online book], <https://proxy.library.brocku.ca/login?url=http%3a%2f%2fsite.ebrary.com%2fflib%2foculbrock%2fDoc%3fid%3d10070207> (accessed January 6, 2010).

⁶² Heinz Klug, "Law, Politics, and Access to Essential Medicines in Developing Countries," *Politics and Society* 36, no.2 (June 2008): 212.

Beyond Corporations: "The Third Force"⁶³ of Transnational Non-State Actors

The rise of transnational corporations and some of their activities created issues that caught the attention of a variety of non-governmental stakeholders including civil society organizations and consumers. Based on the (contested) assumption that corporations have responsibilities beyond profit and duty to shareholders, there has been a movement to hold business accountable for the negative impacts their activities may have on societies. Pressure exerted by states and civil society organizations on corporations concerning practices and outcomes has resulted in the development in many industries of a guiding set of principles and norms that constitute corporate social responsibility.⁶⁴

As John Ruggie argues, the push for corporate responsibility is partially due to the perception that while rules that promote the market have progressed rapidly, they have not been balanced against other valid social concerns.⁶⁵ Therefore, actors that were not previously engaged in issues such as trade have been prompted to enter into new arenas to become proponents for change.⁶⁶ The range of actors now participating in governance (sets of rules, institutions and practices) at the international level has created what he calls a new global public domain where "expectations regarding legitimate social purposes, including the respective roles of different social sectors and actors, are articulated, contested, and take shape as social facts."⁶⁷

⁶³ From the title of a book edited by Ann M. Florini, *The Third Force: The Rise of Transnational Civil Society* (Tokyo: Japan Center for International Exchange and US: Carnegie Endowment for International Peace, 2000).

⁶⁴ A. Claire Cutler, "Transnational Business Civilization, Corporations, and the Privatization of Global Governance," in *Global Corporate Power*, ed. Christopher May (US: Lynne Rienner Publishers, 2006), 200.

⁶⁵ John Gerard Ruggie, "Reconstituting the Global Public Domain – Issues, Actors, and Practices," *European Journal of International Relations* 10, no.4 (2004): 511.

⁶⁶ *Ibid.*, 508.

⁶⁷ *Ibid.*, 504.

The actors participating and competing in the global public domain now include states, international organizations and a host of non-state actors including corporations, civil society organizations, consumers and citizens. To understand the impact they may have on state behaviour, we will now consider social constructivist theory.

Social Constructivism

In much of the recent international relations literature, social constructivist theory has been the framework employed to analyze the contribution of non-state actors toward state behavior. Considered to be a meta-theory, “constructivism is concerned with human consciousness”⁶⁸ and the effect this has on state identities and interests. Ruggie traces the underlying premise to Max Weber and John Searle who argued that humans have the ability to give “significance” to their existence and have created “social facts” to guide their interactions.⁶⁹ Therefore, the core assumption of constructivism is that human actions are founded on intersubjective understandings of the world around them.⁷⁰

Constructivism holds that social interactions are underpinned by collectively shared beliefs or meanings, which are rooted in ideational rather than material factors, and that the formation of identities and interests is intrinsically linked to these beliefs.⁷¹ The belief system is not viewed as individually held, rather it is perceived as a “collective intentionality” that brings legitimacy to the reality it constructs. Further, constructivists suggest that constitutive rules logically precede the construction of institutions. Through

⁶⁸ John Gerard Ruggie, “What Makes the World Hang Together? Neo-utilitarianism and the Social Constructivist Challenge,” *International Organization* 52, no. 4 (Autumn 1998), 878.

⁶⁹ *Ibid.*, 856.

⁷⁰ *Ibid.*, 856.

⁷¹ Martha Finnemore and Kathryn Sikkink, “Taking Stock: The Constructivist Research Program in International Relations and Comparative Politics,” *Annual Review in Political Science* 4 (2001), 393. See also Friedrich V. Kratochwil, *Rules, Norms and Decisions: On the Conditions of Practical and Legal Reasoning in International Relations and Domestic Affairs* (Cambridge: Cambridge University Press, 1989) and Alexander Wendt, *Social Theory of International Politics* (Cambridge: Cambridge University Press, 1999).

constitutive rulemaking the agreed-upon constructed reality is first shaped and reinforced. This reality may become formalized by the creation of institutions that will craft and promulgate regulative rules, further affecting state identities, interests and relationships.⁷²

Constructivists argue that the “international structure is determined by the international distribution of ideas.”⁷³ International norms, defined as “a standard of appropriate behavior for actors with a given identity,”⁷⁴ provide the collective understandings that promote international order. Norms require both belief and action consistent with the belief to be internalized; however, states’ interpretation of and compliance with international norms may not be static but reflective of their domestic processes and actors.⁷⁵

Within the constructivist framework of analysis, structure and agent are considered to be mutually constitutive, without prior and fixed positions. Subsequently, the role of ideas, norms and culture becomes increasingly important in explaining individual state preferences and shifts in policy.⁷⁶ If the reality in which states operate is socially constructed, it is possible that the introduction of different ideas, knowledge or practices could allow for the re-conceptualizing of a state’s identity and interests. When a critical mass of states similarly adjust their beliefs or practices, new international norms may be accepted and institutional change may follow.

⁷² Ruggie, “What Makes,” 869-870.

⁷³ Martha Finnemore and Kathryn Sikkink, “International Norm Dynamics and Political Change,” *International Organization* 52, no.4 (Autumn 1998), 891-894.

⁷⁴ *Ibid.*, 891-894.

⁷⁵ Thomas Risse and Kathryn Sikkink, “The socialization of international human rights norms into domestic practices: introduction,” in *The Power of Human Rights: International Norms and Domestic Change*, ed. Thomas Risse, Stephen C. Ropp, and Kathryn Sikkink (UK: Cambridge University Press, 1999), 7.

⁷⁶ Finnemore, “Taking Stock,” 392-393.

Constructivists have begun to analyze factors that may contribute to changes in state behaviour, and a body of literature specifically around the role of civil society and transnational advocacy has emerged. Consistent with the claim that advocacy groups seek “to create, strengthen, implement, and monitor international norms,”⁷⁷ the literature includes a typology of the groups and the scope of the activities that individuals participate in to effect change, the type of issues they address and the techniques that are used by non-state actors to encourage states to redefine roles and adopt new norms.

For the purpose of this paper, I have adopted the distinctions made by Khagram et al. who argue that there are four ideal types involved in transnational advocacy. All types include actors that are somehow connected across state borders, but how they are organized and the mechanisms they employ add to the distinction between groups. The first, international nongovernmental organizations, “have a decision-making structure with voting members from at least three countries, and their aims are cross-national and/or international in scope.”⁷⁸ The second type, transnational advocacy networks, are usually identified as having less formalized relationships but are connected by shared values around an issue. Networks can include a variety of actors and their most important resource is the ability to facilitate a rapid and accurate “dense exchange of information.”⁷⁹ Networks do not normally coordinate other kinds of collective action, rather, when a transnational advocacy group becomes more formalized and adopts strategies such as forming campaigns and organizing conferences, this third type is

⁷⁷ Sanjeev Khagram, James V. Riker, and Kathryn Sikkink, “From Santiago to Seattle: Transnational Advocacy Groups Restructuring World Politics,” in *Restructuring World Politics: Transnational Social Movements, Networks, and Norms*, ed. Sanjeev Khagram, James V. Riker, and Kathryn Sikkink (US: University of Minnesota Press, 2002), 4.

⁷⁸ Ibid., 6.

⁷⁹ Ibid., 7, 9.

identified as a transnational coalition. The members of the coalition can also include a wide variety of actors from international and domestic locales who are likely to maintain close contact in order to coordinate their efforts toward a specific goal.⁸⁰

The final type identified by Khagram et al. are transnational social movements and are defined as “sets of actors with common purposes and solidarities linked across country boundaries that have the capacity to generate coordinated and sustained social mobilization.”⁸¹ Transnational social movements are less common because their activities require a high degree of coordination to be jointly mobilized in at least three states. The tactics used to publicly promote change typically include protests and other disruptive activities designed to bring attention to the issue.⁸²

Advocacy groups are assumed to lack traditional power and must instead rely on the ability to create influence through the strategic use of information and to act as moral entrepreneurs. By creating a specific discourse in an issue-area, advocacy groups use what some authors refer to as soft⁸³ or communicative power to introduce new norms or use persuasion to re-shape existing norms.⁸⁴ Comprised mainly of non-governmental organizations, they are seen as part of the third sector of international actors, who unlike states and businesses, conduct their activities primarily based on principled beliefs that invoke notions of what ‘ought to be.’⁸⁵ In contrast, states have military and economic

⁸⁰ Ibid.

⁸¹ Ibid., 8.

⁸² Ibid.

⁸³ Joseph Nye defines soft power as including “culture, beliefs, values and ideals” in contrast to hard power which is typically military or economic means used to coerce or influence behaviour. See Balaam and Veseth, 11.

⁸⁴ Kathryn Sikkink, “Restructuring World Politics: The Limits and Asymmetries of Soft Power,” in *Restructuring World Politics: Transnational Social Movements, Networks, and Norms*, ed. Sanjeev Khagram, James V. Riker, and Kathryn Sikkink (US: University of Minnesota Press, 2002), 303-304.

⁸⁵ Khagram, 11.

power that can be used as coercive mechanisms, while businesses may enjoy economic resources and participation in industry networks that can influence governments.

Keck and Sikkink categorized the mechanisms used by advocacy groups into four types of political actions: information, symbolic, leverage and accountability.⁸⁶ Information politics includes the relevant and timely gathering of facts, statistics, alternate interpretations, and testimony that may be used to frame an issue, refute claims, and build legitimacy for the advocacy group in the issue-area.⁸⁷ Framing is used by advocacy groups to “define the issues at stake and the appropriate strategies for action”⁸⁸ and must be crafted to resonate with the targeted audience in order to persuade them of what ought to be. Symbolic politics may involve using one or more events to frame an issue and raise awareness within a wider audience, and may be used by groups to raise their own profiles to create a perception of legitimacy.⁸⁹ The third category, leverage politics, is in response to the asymmetrical power structure that issues are negotiated within. Advocacy groups will seek leverage over more powerful actors through material or moral means, which may include linking policy options to “money or goods” or exposing actors’ behaviors to scrutiny through “shaming.”⁹⁰ Finally, accountability politics is used by advocacy groups to call attention to the disparity between an actor’s commitment in principle and its actual practice, and is based on the assumption that states are more likely to comply when they risk being embarrassed.⁹¹

⁸⁶ Keck and Sikkink, *Activists beyond Borders*, 16.

⁸⁷ Ibid., 18-22.

⁸⁸ Finnemore and Sikkink, “Taking Stock,” 409.

⁸⁹ Keck and Sikkink, *Activists beyond Borders*, 22-23.

⁹⁰ Ibid., 23.

⁹¹ Ibid., 24.

One area of theoretical disagreement arises in Keck and Sikkink's defining advocacy networks as different from interest groups in that they are motivated by "principled beliefs or values."⁹² Sell and Prakash argue that analytically there is no difference between interests and ideas, and that many instrumental actors also demonstrate principled beliefs while advocacy networks similarly may be concerned with the material.⁹³ They argue that although business networks are profit-oriented, they can also be viewed as competing interest groups that use strategies similar to advocacy networks to pursue their policy goals. For Sell and Prakash,

Success in influencing policy processes lies not in claimed moral superiority of the agenda but in the network's superior abilities to create and make the most of political opportunities by exploiting a crisis, constructing a problem, mobilizing a coalition, and grafting its agenda onto policy debates.⁹⁴

For the purpose of this paper, I will continue to use advocacy networks as defined by the former, but in terms of outcomes and strategies, I concur with the latter point.

Keck and Sikkink have argued that networks tend to be more successful when the issue involves ideas of right and wrong, especially when there is "bodily harm to vulnerable individuals"⁹⁵ and blame can be assigned to parties responsible. This would suggest that issues that employ a human rights perspective may be more effective.

Human rights norms have been increasingly accepted by the international community in concept and practice since the Universal Declaration of Human Rights was adopted in 1948. The main body of rights that have been forwarded as being universal and extending to all humans in order to protect human dignity are included in nine core

⁹² Ibid., 1.

⁹³ Sell and Prakash, 147-149

⁹⁴ Ibid., 149.

⁹⁵ Keck and Sikkink, *Activists beyond Borders*, 26-27.

international treaties monitored by the United Nations.⁹⁶ By ratifying participation in a treaty, states are bound “to protect, to respect and to fulfil” the enjoyment of human rights contained within and to implement necessary measures to facilitate states’ obligations toward this end.⁹⁷

However, human rights are contested by some as being a construct of the “West” and parochial in nature because they “reflect (1) an arbitrarily restricted set of moral values; or (2) an arbitrary ranking of certain moral values.”⁹⁸ In spite of these objections, all member states of the UN have ratified at least one major treaty and 80% of states have ratified at least four.⁹⁹ This implies that the understandings of the obligations undertaken by states may not be uniform and that different conceptualizations may be present. Negotiations are often lengthy with results that exceed the capacity or desire of many states and enforcement mechanisms are weak. Therefore, the adoption of human rights treaties by states is frequently interpreted as signaling a long term aspiration toward respecting rights rather than a guarantee of rights.¹⁰⁰

There are two significant considerations in recognizing rights. First, rights imply that the individual has a claim against the state for the recognition of both positive and negative rights. Negative rights mean the right-holder assumes there is an obligation by the state to refrain from certain violations against an individual, such as the right not to be tortured. Positive rights assume that the state will take certain actions to provide

⁹⁶ United Nations High Commissioner for Human Rights, <http://www2.ohchr.org/english/law/> (accessed Sept. 10, 2010).

⁹⁷ United Nations, International Human Rights Law, <http://www.ohchr.org/EN/ProfessionalInterest/Pages/InternationalLaw.aspx> (accessed May 14, 2010).

⁹⁸ Allen Buchanan, *Human Rights, Legitimacy, and the Use of Force* (NY: Oxford University Press, 2010): 72.

⁹⁹ United Nations, Human Rights Bodies, <http://www.ohchr.org/EN/HRBodies/Pages/HumanRightsBodies.aspx> (accessed May 14, 2010).

¹⁰⁰ Eric Neumayer, “Do International Human Rights Treaties Improve Respect for Human Rights?” *Journal of Conflict Resolution* 49, no.6 (Dec.2005): 928.

something for the individual, such as the creation of a public health care system to enjoy the right to health. This places a burden on the state that may not coincide with state resources and capacity economically or administratively.

The second problem with recognizing human rights as guaranteed is that rights may conflict with other interests a state needs to pursue. The state may justify violating individual human rights for cultural reasons or for the benefit of a larger constituency.¹⁰¹ More importantly, state preferences will hierarchically determine policy concerns and the allocation of resources accordingly. For realists, the main policy concern is security and all other policies would be subservient to the preservation of security. In contrast, liberal theorists claim that human rights norms are prominent on the agendas of liberal states and are important in how states identify themselves to others as a “member of the community of liberal states.”¹⁰² However, when viewed through a constructivist lens, states are not merely rational actors, but generally “try to do the right thing.”¹⁰³ Therefore, pressure on governments from below through domestic processes or from above by transnational advocacy networks may be effective in moving states closer to internalization and compliance of human rights norms.¹⁰⁴

Several international treaties and documents include the right to health as a fundamental human right, in some cases noting its prerequisite status for the realization of other rights. First appearing in the Constitution of the World Health Organization (WHO) in 1946, the right to health is generally framed as “the right to the enjoyment of

¹⁰¹ Buchanan, 72-73.

¹⁰² Risse and Sikkink, 8-9.

¹⁰³ Thomas Risse, ““Let’s Argue!”: Communicative Action in World Politics,” *International Organization* 54, no.1 (2000): 4.

¹⁰⁴ Neumayer, 930-932.

the highest attainable standard of physical and mental health”¹⁰⁵ and is enumerated in Article 12.1 of the International Covenant on the Economic, Social and Cultural Rights (ICESCR). As a social right, the right to health has been most clearly qualified by the United Nations Social and Economic Council in a report released in August 2000.¹⁰⁶ The document notes that the right to health is not absolute, rather it is subject to state resources and socio-economic factors, and still is for millions “a distant goal.”¹⁰⁷ However, the report clarifies that all states are required to steadily work towards realization of the goal, and in recognizing the inequality of resources between states, reminds the international community that it has an obligation to assist other states, particularly developing countries, in attaining health goals. This obligation includes ensuring the right to health is not restricted through other international agreements, nor constrained by economic sanctions or other punitive measures.¹⁰⁸ Finally, the right to health is conceptualized in the report as including access to affordable medicines as defined on the WHO Model List of Essential Drugs.¹⁰⁹

Hogerzeil et al. report that over 150 countries have ratified the ICESCR and over 100 states have taken the additional step of embedding the right to health into their constitutions. In their analysis of 71 cases that were litigated in national courts mostly in

¹⁰⁵ For example, the same or similar wording is included in the Universal Declaration of Human Rights, 1948, the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, the Declaration of Alma-Ata (Health for All), 1978, and the Covenant of the Rights of the Child, 1989.

¹⁰⁶ United Nations Economic and Social Council, “The right to the highest attainable standard of health: 11/08/2000.” *E/C.12/2000/4. General Comments*, [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En) (accessed May 1, 2010).

¹⁰⁷ *Ibid.*, pt. 4, 5.

¹⁰⁸ *Ibid.*, pt. 38, 39.

¹⁰⁹ *Ibid.*, Pt. 43(d). The World Health Organization is an agency of the United Nations. It began the Model List of Essential Medicines in 1977 and updates the list every two years, the most recent being March 2009. According to WHO, the list is not intended to comprise a global standard, rather, it is a framework for national governments to adapt their individual needs to based on burden of disease and economic factors affecting health policy. Drugs on the list are considered the most necessary for ongoing global health, and are generally expected to be accessible, affordable and of appropriate quality and dosages at all times. More about the selection of essential medicines is available at http://www.who.int/selection_medicines/en/

Central and Latin America, the authors note that 80% argued a linkage between the right to health and the right to life, and a quarter of the successful cases invoked an international human rights treaty as evidence of state responsibility.¹¹⁰ This suggests that the right to health may be gaining wider international recognition in both principle and practice and is inserting itself into customary international law that is accepted by states with a variety of resource capacities.

In this case study, the role of epistemic communities is also considered. An epistemic community consists of experts and researchers who have “specialized knowledge” in an issue-area and who may be instrumental in constructing new norms. Epistemic communities often have shared understandings of an issue and how it should be addressed and can use their knowledge to add a perception of authority to their assertions. In addition, their technical expertise may be sought by relevant policy-making actors and may provide access points within governments and international organizations that advocacy groups may otherwise find difficult to gain.¹¹¹

The advocacy campaign addressed in this paper is a relevant case study to explore the identity and role of advocacy groups and the mechanisms used, and to identify key factors that added to the salience of the campaign and its effect on state behaviour. For the purpose of this paper, I adopt Keck and Sikkink’s definition of campaigns as “processes of issue construction” where “activists identify a problem, specify a cause,

¹¹⁰ Hans V. Hogerzeil, Melanie Samson, Jaume Vidal Casanovas and Ladan Rahmani-Ocra, “Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?” *Lancet* 368 (July 2006): 306-311. Of the 71 cases, 59 were successful in the courts, and of these, 10 were supported and in some cases financed by NGOs.

¹¹¹ Finnemore and Sikkink, “Taking Stock,” 401-402.

and propose a solution, all with an eye toward producing procedural, substantive, and normative change.”¹¹²

¹¹² Keck and Sikkink, *Activists beyond Borders*, 8.

Chapter 2

The World Trade Organization (WTO) was created during the Uruguay Round of negotiations which occurred from 1986 to 1994 between the contracting state parties to the *General Agreement on Tariffs and Trade* (GATT). When it entered into legal existence on January 1, 1995, the WTO was designed to overcome many deficiencies evident in the previous multilateral trade agreement, and it incorporated additional areas of trade including intellectual property rights and trade in services.

As World War II came to a conclusion in the mid-1940s, the allied states recognized the need to formalize trade rules that would enhance efforts of reconstruction and promote international economic cooperation. The United Nations Economic and Social Committee assumed the leadership to design a charter for the proposed International Trade Organization (ITO). Simultaneously, the United States and its allies negotiated the GATT as a provisional multilateral trade agreement which came into force in 1947, and it remained the primary treaty concerning trade rules and tariffs when plans for the ITO were ultimately abandoned. However, the GATT's ability to act as a binding legal entity was undermined because it lacked the institutional framework that was to have been realized through the ITO. Consequently, the GATT did not have the mechanisms necessary for effective oversight and enforcement of trade agreements, including adjudication of disputes and enforcement of decisions.

The terms of the GATT also allowed for inconsistencies in the observance of trade rules. While the GATT existed as a multilateral treaty, it contained exemptions that permitted states to “grandfather” some types of domestic legislation that had been in force prior to accession, further weakening the ability to regulate trade.¹¹³ Another

¹¹³ Mitsuo Matsushita, Thomas J. Schoenbaum, and Petros C. Mavroidis, *The World Trade Organization, Law, Practice, and Policy* (New York: Oxford University Press, 2003), 2-3.

factor affecting consistency was that new trade measures and amendments to existing rules under the GATT were negotiated as separate treaties and states were not obliged to accept and abide by all provisions. This practice was similar to entering into other international treaties where states could accept in principle the terms within the treaty, yet could register reservations on particular aspects. In 1990, states considered the “Canadian proposal” which addressed the problems posited by the piecemeal structure of trade treaties and agreed to form a new trade organization that would “be acceded to as a single undertaking.”¹¹⁴ Under this proposal, contracting states would have to agree to be subject to all provisions to gain and retain membership in the new World Trade Organization.

To avoid the weaknesses within the GATT, the formation of the World Trade Organization was supported by a charter and a single body of law comprised of a revised GATT plus various trade related agreements and legal instruments. All member states are now obliged to observe the rules of the WTO, and additional agreements or amendments to trade policies are reached through consensus during negotiating rounds and become binding. In addition, structural mechanisms are in place to enable the WTO to perform specific responsibilities on behalf of the Members including trade negotiations, dispute resolution, and policy monitoring, as well as the authority to engage in collaborative undertakings with other international organizations such as the International Monetary Fund and the World Bank.¹¹⁵

¹¹⁴ Klug, 216.

¹¹⁵ Matsushita, 7-9.

Intellectual Property Rights and the relationship to trade

Included in the 1994 documents negotiated during the Uruguay Round was the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). This document provides international harmonization of IP rights and obligations, including the “scope, subject matter and duration of IP protection”¹¹⁶ as well as a mandate for supporting civil and criminal procedures. While recognition and protection of intellectual property rights had been a consideration of states for more than a century, it was never addressed under the GATT. Prior to inclusion within WTO agreements, intellectual property rights were primarily administered at the international level through a special agency of the United Nations, the World Intellectual Property Organization (WIPO).

WIPO was established in 1967 with a primary objective “to promote the protection of intellectual property throughout the world through cooperation among States,”¹¹⁷ and it oversaw twenty-three treaties pertaining to patents, inventions, industrial design and copyright. Recognition of the need for IP protection in these instruments dates back to the 1883 *Paris Convention for the Protection of Industrial Property* dealing with the protection of inventions, trademarks and industrial design, and the 1886 *Berne Convention for the Protection of Literary and Artistic Works* acknowledging copyright.¹¹⁸ However, revisions to IP agreements under WIPO were difficult to achieve and to administer because of the need for consensus among member states, and similar to the deficiencies

¹¹⁶ Sell, *Private Power*, 12.

¹¹⁷ WIPO, “Convention Establishing the World Intellectual Property Organization,” Article 3(1), http://www.wipo.int/treaties/en/convention/trtdocs_wo029.html#P68_3059 (accessed March 27, 2010).

¹¹⁸ Information about and texts of the treaties administered by the World Intellectual Property Organization are accessible on the website at www.wipo.int/treaties/en

experienced under the GATT, treaties and international conventions lacked enforcement mechanisms and provided no forum for grievances between states.¹¹⁹

More importantly, intellectual property rights were assured only through individual state preferences, policies and regulatory frameworks. As Sell notes, states were free to decide the extent of protection offered based on individual stages of development and capacity for “either innovation or imitation.”¹²⁰ This led to marked inconsistencies in domestic laws for both the issuing of patents and the enforcement of patent law. Most states traditionally viewed intellectual property rights as a form of protectionism or as an instrument used to secure a monopoly over a product or invention, so were cautious in adopting broad legislation that would recognize rights. In essence, patent holders had considerable control over where a product or process could be worked, its output and price, and could even decline to allow its use.¹²¹ Even in the U.S. until the early 1980s, intellectual property rights were viewed as a “grant of privilege” and anti-trust laws were designed to ensure fair competition.¹²²

The recognition of IP rights between states originated in Europe in the 1800s as concerns arose over reproduction of books and copying of new industrial inventions. Some states entered into bilateral treaties which eventually led to the *Paris* and *Berne Conventions*.¹²³ Under the *Paris* and *Berne Conventions* states were not specifically required to recognize or regulate intellectual property rights, however, when states did choose to adopt regulations, they were then expected to extend that protection to nationals and foreigners alike. In addition, there was no commonly recognized approach

¹¹⁹ Matsushita, 398.

¹²⁰ Sell, *Private Power*, 12.

¹²¹ *Ibid.*, 13–14.

¹²² *Ibid.*, 5

¹²³ *Ibid.*, 11.

or minimum standard set by the *Conventions*, so states were allowed flexibility to interpret which industries were to be included under their regulatory framework and to what extent they were to be regulated.¹²⁴

Pharmaceuticals posed a particularly difficult problem for establishing IP rights under the *Paris Convention*. Some states would not extend any protection to pharmaceuticals, preferring to view them as a public good. Many states drew a regulatory distinction between the invention of a product and the process through which the invention was manufactured, and allowed different treatment of the two. In some states, such as India, patenting was available for process but not for product, and reverse engineering allowed for the growth of a dynamic generic industry.¹²⁵ Many less developed countries did not issue patents for pharmaceuticals because they lacked the research or manufacturing capacity to warrant the cost of providing IP protection, and it was estimated at the beginning of the Uruguay Round that about forty states were in this category that did not grant patents for the invention of medicines.¹²⁶

In states where patents were issued for pharmaceuticals, the length of time for enforcement varied, and medicines were frequently granted a shorter patent life than other less essential inventions and products.¹²⁷ Many governments were concerned that patents would create a barrier to accessing necessary medicines during an outbreak or health crisis, and had at one time incorporated aspects of parallel importing and

¹²⁴ Klug, 211.

¹²⁵ Jan Peter Wogart, "From Conflict over Compromise to Cooperation? Big Pharma, the HIV/AIDS Crisis and the Rise of the Countervailing Power in the South," in *Global Health Governance and the Fight Against HIV/AIDS*, ed. W. Hein, S. Bartsch and L. Kohlmorgen (Basingstoke U.K.: Palgrave Macmillan, 2007), 71.

¹²⁶ Klug, 211.

¹²⁷ Pedro Roffe, Christoph Spennemann and Johanna von Braun, "From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health," in *Negotiating Health: Intellectual Property and Access to Medicines* (U.K.: Earthscan, 2006), 11.

compulsory licensing provisions within their legislation. However, most states had revised their laws and had removed these flexibilities under pressure from the U.S. in the years leading up to the Uruguay Round.

Further complicating IP protection, was that the patent regime relied on a registration system and enforcement mechanisms, both judicial and administrative, that fell under the purview of the individual state. Not all states had the institutional capacity to create and maintain a registry or the political will to follow through with regulatory enforcement.

Linking Trade Issues to the Protection of Intellectual Property

The inclusion of intellectual property rights on the trade agenda for the Uruguay Round was primarily at the insistence of the United States. Carlos Correa has identified four major factors influencing the U.S.'s urgency to standardize IP laws internationally, which include its increasing trade deficit, a weak international IP regime, newly emerging export markets, and the pressure of an intense lobby effort by a coalition of affected industries.¹²⁸

The U.S. had experienced a rapidly escalating trade deficit in the early 1980s, and international trade in high-technology goods became increasingly important to all industrialized countries for maintaining comparative advantage. Private sector industry responded by investing in research and development of more advanced products and services, and the number of transnational corporations was flourishing.¹²⁹

Secondly, the U.S. had increased IP protection domestically in recognition of the high externalities generated by research and development in areas such as computer software and biotechnology, and had sought to enhance exclusivity rights internationally. This

¹²⁸ Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries* (London: Zed Book Ltd., 2000), 3-4.

¹²⁹ Ibid., 3.

was frustrated by the many developing states that had little interest in, or benefit from, regulating and enforcing patents. The U.S. sought, mostly through bilateral trade agreements, to pressure other states into adopting its standards.¹³⁰

Thirdly, because the U.S. was actively engaged in creating bilateral and regional free trade agreements, new export markets had emerged. As international trade barriers decreased, transnational corporations saw attractive new options for reducing the burden of technology transfer and localized production.¹³¹

Finally, and more importantly to this paper, powerful business groups had successfully lobbied the government for a decade leading up to the Uruguay Round and had convinced policy makers that the declining position of U.S. firms in knowledge-intensive areas was directly related to a weak intellectual property regime. This was viewed not only as contributing to the increasing U.S. trade deficit, but also as a major threat to future investment in research and development.¹³²

Through their lobby effort, transnationals were able to convince U.S. policy makers that the interests of government and corporations had increasingly converged throughout the late 1970s and 1980s, and the impact of the interconnectedness between trade issues, financial investment and economic stability was beginning to emerge.¹³³ By pressuring the U.S. Congress to revise its trade laws, the lobbyists succeeded in institutionalizing the link between trade and intellectual property rights.¹³⁴

¹³⁰ Ibid., 3-4.

¹³¹ Ibid., 4.

¹³² Ibid.

¹³³ Klug, 212.

¹³⁴ Susan K. Sell and Aseem Prakash, "Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights," *International Studies Quarterly* 48 (2004): 159.

The Corporate Initiative and the United States Trade Representative

In 1986, the U.S. based Intellectual Property Committee was formed by representatives from industries most affected by weak IP protection including pharmaceuticals, chemicals, computer software, and entertainment.¹³⁵ Their claim was that the inability to adequately protect products and processes through patent and copyright laws had resulted in an increase in the production of counterfeit goods, particularly in newly industrializing countries. As the availability of less expensive counterfeit or generic products increased, trade in legitimate goods had declined.¹³⁶

In addition, industry lobbyists promoted forum-shifting to seek better IP protection. They advocated for the movement of IP protection from WIPO to the GATT because of their perception that structurally, WIPO was too sympathetic to developing states. Pfizer, one of the largest pharmaceutical corporations and leader of the lobby group, had previously attempted to institute reforms to the *Paris Convention* within this venue. However, because each of the contracting state parties is allowed one vote under WIPO, developing countries formed the majority of Member states and could prevent initiatives attractive to the corporate interests of the wealthier states. Frustrated in its bid to influence change at WIPO, Pfizer and other corporations formed a coalition which turned its attention to U.S. Congress, and in conjunction with the Pharmaceutical Research and Manufacturers Association, began to lobby for changes in the GATT.¹³⁷

Sell and Prakash argue that IP business interests were skillfully framed as property rights, and as such, were perceived as “somehow natural, unassailable, and automatically

¹³⁵ Sell, *Private Power*, 2. Sell notes that the pharmaceutical companies on the IPC in 1986 included Pfizer, Merck, Johnson and Johnson and Bristol-Meyers.

¹³⁶ Sell and Prakash, 153.

¹³⁷ Klug, 212.

deserved.”¹³⁸ This was an important perceptual shift from a “grant of privilege,” bestowed by government, to the claim of a right that was somehow being violated, through technically legal means.¹³⁹ The lobby group adopted language that presented themselves and by extension, the U.S. economy and American public, as victims of a form of “piracy” that could be prevented by a strengthened IP regime. Advances in technology meant that ideas and inventions were more vulnerable to appropriation by firms that had not invested in the research phase, and these firms were viewed as free-riders that could undermine the legitimate market by producing copies or ‘similars’ inexpensively.¹⁴⁰ Citing a study conducted by the U.S. International Trade Commission, the corporate lobby noted that industry had lost US\$43 – 61 billion in 1986 alone due to poor international IP protection.¹⁴¹

Persuaded by the lobby group’s arguments, the U.S. Congress had passed amendments to their domestic trade laws in 1979, 1984 and 1988 that had strengthened IP protection. The latter of these defined the role of the United States Trade Representative (USTR) and created Section 301 powers commonly referred to as Special and Super 301 which could be used to put pressure on, and retaliate against, states that did not comply with U.S. trade expectations. Section 301 compelled the U.S. Trade Representative to investigate and report annually on IP laws and compliance, and “watch lists” were created to add to the pressure placed on states that the U.S. perceived as engaging in unfair practices or that were offering weak intellectual property enforcement.¹⁴²

¹³⁸ Sell and Prakash, 157.

¹³⁹ Ibid., 157-158.

¹⁴⁰ Sell, *Private Power*, 14. Also, Sell and Prakash, 154-157.

¹⁴¹ Sell and Prakash, 155. The authors note that the study may be inaccurate due to incentives to exaggerate losses in this study that relied on self-reporting, however, they note that there was no real challenge to the figures.

¹⁴² Klug, 213.

In addition, under the revised U.S. trade law, the private sector was permitted to petition the USTR to take measures to protect their IP rights. The pharmaceutical industry, for example, skillfully pursued this option and was particularly successful in its bid, through the USTR, to influence revision of IP laws affecting medicines in several states between 1987 and 1993, including South Korea, Thailand and Canada.¹⁴³

Industry executives also recognized the need to lobby beyond the U.S. government to ensure international IP protection. The Intellectual Property Committee developed a proposal for a more comprehensive IP treaty and submitted it to the GATT Secretariat in 1988, laying the foundation for its inclusion in trade talks.¹⁴⁴ In addition, the Committee networked with similar organizations in Europe and Japan. Together they developed a strategy to persuade their home governments to support the inclusion of IP in negotiations during the Uruguay Round.¹⁴⁵

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

During the Uruguay Round, a number of developing and lesser developed countries initially resisted the TRIPS Agreement because they recognized that stricter adherence to IP rights was primarily in the interest of developed countries. However, many of the key states needed to strengthen the opposition were not aligned because the U.S. Trade Representative had engaged in coercive tactics for several years prior, threatening Section 301 economic sanctions against states with poor or no IP laws. As a result, states such as Thailand, Chile and South Korea, and many of the more industrialized countries, had

¹⁴³ Ibid., 212-213.

¹⁴⁴ Sell, *Private Power*, 2.

¹⁴⁵ Sell and Prakash, 157.

been pressured into making IP revisions or had entered into bilateral trade agreements with the U.S. that already exceeded proposed international IP standards.¹⁴⁶

Furthermore, the TRIPS Agreement was to be included as part of the total trade package under the WTO. Other benefits of the new regime were to include the recognition of “most favoured nation,” new and expanded markets in agriculture and textiles, and opportunities for technology transfer. Most states were persuaded that the advantages of the package outweighed the drawbacks of the TRIPS Agreement, and eventually the opposition to “TRIPS” by developing states was diminished.¹⁴⁷

The TRIPS Agreement, *Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization*, came into force on January 1, 1995. The preamble states that the purpose is “to reduce distortions and impediments to international trade” and “to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”¹⁴⁸ The agreement attempts to standardize for Member states their minimum obligations to other states in their treatment of patent holders in all areas of technology, as well as covering copyright, industrial designs, trademarks and other areas of intellectual property. It incorporates the standards of the *Paris* and *Berne Conventions*, as well as new requirements. The agreement initially allowed developing countries to phase in the rules, with all state parties to be compliant by January 1, 2005, although the timeline was later extended in the area of pharmaceuticals for developing countries, with the least developed not required to adapt until 2016.

¹⁴⁶ Klug, 213-217.

¹⁴⁷ Ibid.

¹⁴⁸ WTO, “Uruguay Round Agreement: TRIPS, Preamble,”

http://www.wto.org/english/docs_e/legal_e/27-trips_02_e.htm (accessed April 13, 2008).

Compliance required that states adopt domestic legislation and establish a regulatory framework for substantive minimum standards of intellectual property rights, including enforcement and remedies, judicial review, border procedures that allow for control, and an office for IP application and management. In addition, member states became subject to multilateral dispute and adjudication mechanisms established at the WTO through the Dispute Settlement Body.¹⁴⁹

The TRIPS Agreement and Pharmaceuticals

The TRIPS Agreement required states to grant patent rights for pharmaceuticals for both product and process for a twenty year period.¹⁵⁰ This time frame was viewed as the minimum necessary to provide incentives for future investment in research and development. Pharmaceutical companies defended the position by arguing that drug research and development is an extremely expensive and longer term proposition, whereas producing a generic drug from an already developed invention and technology can be achieved very cheaply by those with no interest in re-investment. Pharmaceutical producers relied on patent protection to recover their research costs by generating profits from the distribution and sales of medicines to the first generation of users. In addition, they claimed that financial investment in drug research is higher than in any other knowledge intensive industry.¹⁵¹

The TRIPS Agreement contained some flexibilities, although their interpretation remained contentious and eventually led to further negotiations. The principles as outlined in Article 8 permitted states to consider their individual policy interests and to

¹⁴⁹ Matsushita, 405-406

¹⁵⁰ WTO, "Uruguay Round Agreement: TRIPS, Section 5," http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (accessed October 6, 2010).

¹⁵¹ Phillippe Cullet, "Patents and medicines: the relationship between TRIPS and the human right to health," *International Affairs* 79, no.1 (2003): 141.

interpret the TRIPS Agreement in a manner that allowed them to protect public health. Article 27.1 stated patents were for ‘inventions’ that were ‘new’ and ‘inventive’ but did not provide definitions, which allows room for interpretation at the national level.¹⁵² The inventions being protected included products and processes, but did not include ‘uses’ which is a distinction that could be invoked to disallow extending a patent for an existing drug for new indications or applications.¹⁵³

Article 31 dealt with the rules for compulsory licensing under which a state can override a patent holder’s monopoly on the product or invention for a limited period of time, usually on an urgent or emergency basis. Before issuing a compulsory license, states would normally attempt to get permission from the patent holder to proceed and must give the holder some remuneration for its use. In the case of pharmaceuticals, this seemed to imply that during a self-identified health crisis, a developing state could issue a compulsory license for the manufacture of necessary medications without permission of pharmaceutical companies holding patents. However, there were also limitations in the agreement that proved to be unhelpful for most of the developing world which lacked manufacturing capacity. The product manufactured under compulsory licensing was to be restricted to domestic use and could not be made primarily for the export market.¹⁵⁴

An additional flexibility available to states was that the TRIPS Agreement did not prohibit the use of parallel importation. Parallel importation allows a state to purchase a product from another state that has legally obtained goods under patent. Also, Article 6 of the TRIPS Agreement stated that parallel importing could not be considered grounds

¹⁵² Correa, 51.

¹⁵³ Ibid., 55-57.

¹⁵⁴ WTO, “Uruguay Round Agreement: TRIPS, Section 5 and 6,” http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (accessed October 6, 2010).

for complaints to the WTO for dispute resolution. This provision followed “doctrine of exhaustion” case law from the U.S. and E.U., which held that a patent holder may not maintain rights over products and processes past their origin of legal sale or use, where it is assumed that the right holder has already received adequate remuneration.¹⁵⁵ In the case of pharmaceuticals, permitting parallel importing under the TRIPS Agreement implied that states without manufacturing capacity could legally obtain drugs made under patent from other states and could purchase more affordable generic versions when patents expired. Furthermore, because transnational corporations frequently sold pharmaceuticals with differential pricing, states would be able to ‘shop around’ for the best prices.

Article 30 of the TRIPS Agreement also allowed for limited exceptions for the use of patented inventions to further research and development, and states can implement legislation to provide for this flexibility. This is referred to by the WTO as a research or regulatory exception, or a ‘Bolar’ provision.¹⁵⁶ In the case of pharmaceuticals, this exception could allow generic manufacturers to expedite testing and domestic marketing approval in advance of production for a drug coming off patent, and allows the use of data by researchers to build upon existing medicines to formulate more advanced or combined therapies.¹⁵⁷

However, state governments that attempted to enact legislation to facilitate access to medicines quickly ran into interference. Two cases, one that played out in the South

¹⁵⁵ Correa, 81-88.

¹⁵⁶ Ibid., 77-81. He notes there is substantial case law, particularly in the US allowing Bolar exceptions.

¹⁵⁷ Ibid. See also WTO, “TRIPS Fact Sheet: TRIPS and Pharmaceuticals, Obligations and Exceptions,” http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#bolar (accessed April 24, 2010).

African courts and another against Brazil where a complaint was filed at the WTO, highlighted the problems associated with the intellectual property rights regime.¹⁵⁸

South Africa

In 1998, the Pharmaceutical Manufacturer's Association and 39 national and transnational pharmaceutical companies joined together to challenge implementation of the South African government's *Medicines and Related Substances Control Amendment Act, 1997*. South Africa had the largest population of people living with HIV/AIDS, estimated to be over 4 million, and the post-apartheid Mandela government sought to revise its health policies to deal with the crisis. Implementation of the Act would provide the legal framework for the state to override patent rights under compulsory licensing to produce anti-retroviral drugs for the treatment of HIV/AIDS and to make use of parallel importing in order to access less expensive medicines. In addition, the Act contained regulations that placed limitations on certain practices and encouraged transparency for the marketing, distribution and pricing of pharmaceuticals.

Because the WTO system is for state members and not private entities, the corporate alliance pursued its case in the South African Pretoria High Court rather than through WTO Dispute Settlement Body, arguing that certain parts of the Act contravened the state's Constitution and was in violation of state obligations under WTO membership. As David Barnard points out, the lawsuit was more about securing future interests than about immediate threats to sales. At the time that the lawsuit was filed, it was estimated

¹⁵⁸ Although it will not be discussed in this paper, there is a third case of interest contesting the interpretation of the flexibilities in "TRIPS." The European Community brought Canada to Dispute Settlement at the WTO in 1997 claiming that Canada's provision for the research exception for pharmaceuticals and allowing for stockpiling by competitors prior to a drug coming off patent was inconsistent with "TRIPS." In 2000, the WTO Panel ruled that use of the research exception was permitted however, stockpiling was considered to be a violation. Further information is available at WTO Dispute Settlement: DS114, "Canada – Patent Protection of Pharmaceutical Products," http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm (accessed April 24, 2010).

that Africa represented about 13% of the world population, yet accounted for only 1% of the global trade in pharmaceuticals. South Africa's legislation however, was seen as a threat to corporate interests due to its potential to serve as a template for other countries for future trends in health policy, particularly on drug prices with sustained pressure from the threat of compulsory licensing. Drug companies argued that they relied on patents for protecting their market share which generates the profits needed to recover the costs of research. Furthermore, without appropriate compensation, incentives would not exist for the development of new products.¹⁵⁹

The lawsuit drew the attention of several domestic and international civil society groups, many of which were already engaged in activities focused on pharmaceutical access and treatment for HIV/AIDS. Health Action International¹⁶⁰ had alerted non-governmental organizations in 1996 about the issues that could arise for health as a result of the TRIPS Agreement and had organized conferences in conjunction with other NGOs to explore aspects of compulsory licensing, parallel importing and drug price reductions.¹⁶¹ A loose coalition of organizations had formed around the broad issue of access to medicines. When the South African case was launched, transnational organizations including Médecins Sans Frontières and OXFAM, along with South African based Treatment Action Campaign (TAC), and political actors from several states actively lobbied against the pharmaceutical companies' claim.

Civil society groups argued that the actions taken by the wealthy pharmaceutical companies prevented governments from providing medicines to the most poor and

¹⁵⁹ David Barnard, "In the High Court of South Africa, Case No. 4138/98: the Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries," *Kennedy Institute of Ethics Journal* 12, no.2 (2002):164. Also, Sell, *Private Power*, 14.

¹⁶⁰ Health Action International is a non-profit global network of organizations, consumers, and researchers.

¹⁶¹ Sell, *Private Power*, 147.

vulnerable populations. The campaign claimed that a basic right to health existed and governments must be allowed to provide care for their people. Because medicines were too expensive and governments were prevented from taking measures to access cheaper medicines, the coalition claimed that people were dying unnecessarily. The campaign urged corporate interests to consider their moral obligations and weigh this against economic considerations.¹⁶²

The campaign also asserted that there was no significant correlation between the protection of patented pharmaceuticals in developing countries and profits generated for research and development because new drugs were primarily developed for the wealthy populations of the industrialized world. MSF reported that only 11 of the 1,223 new drugs developed between 1975 and 1996 were indicated for tropical diseases that predominantly affected developing countries.¹⁶³ In addition, many drugs were at least partially developed in publicly funded institutions and laboratories, and several newly patented medicines were actually improved versions of older drugs or were indicated for different uses.

The U.S. government initially sided with corporate interests and threatened trade sanctions, urging South Africa to repeal the Act. In June 1998, the USTR withdrew GSP trade benefits¹⁶⁴ and placed South Africa on its Special 301 Watch List. This prompted HIV/AIDS activists from ACT UP in the US to stage a series of protests in several large cities, and during the summer of 1999, demonstrators targeted U.S. Presidential candidate

¹⁶² Thomas Olesen, "In the Court of Public Opinion: Transnational Problem Construction in the HIV/AIDS Medicine Access Campaign, 1998-2001," *International Sociology* 21, no.1 (January 2006): 14-15.

¹⁶³ MSF- Canada, Campaign for Access to Essential Medicines. "How Politics is Failing the Dying," Brochure, date unknown: 3.

¹⁶⁴ GSP is the USTR's Generalized System of Preferences which allows specific products from designated countries as duty-free. The goal of GSP is to promote economic development in the developing world.

Al Gore, whose campaign was supported by the pharmaceutical industry, disrupting speeches and Democratic rallies.¹⁶⁵ South Africa was removed from the Watch List in the fall and President Clinton announced a change in U.S. policy on the issue of drug access for African states during the WTO Ministerial meeting in Seattle; African states would not be penalized for invoking compulsory licensing.¹⁶⁶ The Bush government confirmed this stance shortly after taking office in 2001.¹⁶⁷

The European Union was also protective of its transnational pharmaceutical industry and had backed the U.S. position threatening sanctions against South Africa. Heads of states from France, Switzerland and Germany, as well as the vice-president of the E.U., had visited South Africa in a bid to persuade government leaders to withdraw the legislation.¹⁶⁸ Finally, as the lawsuit returned to court in March 2001, the E.U. Trade Commissioner responded to an open letter from MSF and publicly supported the right of governments to use compulsory licensing in discretionary circumstances. Under mounting public pressure, the E.U. Parliament changed its position and openly urged the drug companies to withdraw their suit.¹⁶⁹

Some of the companies participating in the lawsuit offered to voluntarily reduce prices on specific drugs or to donate certain drugs for specialized treatment, such as for the prevention of mother to child transmission of HIV. The offers tended to be limited in scope and were criticized by NGOs who argued that goodwill was temporary and did not support a government's right to protect the health of its people. The NGOs insisted that

¹⁶⁵ James Orbinski, *An Imperfect Offering: Humanitarian Action in the Twenty-first Century* (Canada: Doubleday, 2008), 356-357.

¹⁶⁶ Sell, *Private Power*, 152-153. Olesen, 21. Orbinski, *An Imperfect Offering*, 356-357.

¹⁶⁷ Olesen, 21. Also Ellen 't Hoen, "TRIPS, Pharmaceutical patents and access to essential medicines: a long way from Seattle to Doha," *Chicago Journal of International Law* 24 (June 2002): 44.

¹⁶⁸ Orbinski, *An Imperfect Offering*, 355.

¹⁶⁹ Olesen, 21.

sustainability for drug access was tied to the ability of a state to produce or import essential drugs at an affordable price.¹⁷⁰

The global reach of the access campaigns brought negative publicity on the drug companies and a lot of pressure from both the North American and European public. MSF International had been awarded the Nobel Peace Prize in 1999 and had launched a new initiative from its Geneva office, the “Access to Essential Medicines Campaign.” In conjunction with the British NGO Oxfam, they organized a global “Cut the Costs Campaign.” Both organizations had extensive media expertise and garnered international support for their opposition to the lawsuit. The campaign participated in “naming and shaming” individual corporations, as they targeted specific companies that were party to the suit.¹⁷¹

In addition, the access group was pursuing price reductions and licensing agreements in several venues. MSF independently negotiated with Indian drug manufacturer Cipla to purchase a generic supply of triple combination therapy drugs for HIV/AIDS in February 2001. Cipla agreed to supply MSF with the drug for \$350 per patient per year, and to governments for \$600 per patient per year, which was considerably less than the \$10,400 GlaxoSmithKline was charging under patent in the U.S. When the announcement was featured in The New York Times, the price discrepancy between patented and generic drugs was forced into the spotlight and supported the NGO’s claim that patented drugs

¹⁷⁰ Sell, *Private Power*, 154.

¹⁷¹ MSF also publicized a list of 20 multinational drug companies in March 2001, with contact names and addresses. See MSF, “Field News: List of the Pharmaceutical Companies Suing South Africa in the Medicines Act Case,” 8 March 2001, <http://www.doctorswithoutborders.org/news/article.cfm?id=824&cat=field-news/> (accessed July 25, 2010).

were unnecessarily expensive.¹⁷² Cipla and MSF followed up by requesting from South Africa licenses for other ARV drugs; Merck responded by also lowering its prices.¹⁷³

Simultaneously, MSF requested that Yale University and Bristol-Myers Squibb lower the price of their ARV d4T on patent in South Africa and permit generic production under voluntary license. With the support of the founding pharmacologist, students held protests urging the administration and drug company to relax the patent, and the announcement was made to do this in March 2001. A second outcome of the publicity was to support the civil society argument that there is not always a correlation between patents and research costs. In the case of d4T, the drug had been developed at Yale with public funding before being licensed to the drug company for manufacture.¹⁷⁴

When the South African case finally reached the Court in March 2001, it was found that one of the articles being challenged was substantively based on text from WIPO's Committee of Experts. This was damaging to the case brought by the pharmaceutical companies.¹⁷⁵ In addition, the Court granted TAC *amicus curiae* (friend of the court) status on behalf of African civil society. As a South African grassroots organization, TAC was primarily interested in promoting access to treatment and was critical of both the government's lack of action and the corporate position. TAC was prepared to testify about the dire need for drug access, the lack of drug research for tropical illnesses and the

¹⁷² Yves Beigbeder, "HIV/AIDS and Global Regimes: WTO and the Pharmaceutical Industry," in *AIDS and Governance*, ed. Nana K. Poku, Alan Whiteside, and Bjorg Sandkjaer (UK: Ashgate Publishing, 2007), 207.

¹⁷³ Sell, *Private Power*, 156.

¹⁷⁴ Sell, *Private Power*, 156. Also, see Donald G. McNeil Jr., "Yale Pressed to Help Cut Drug Costs in Africa," *New York Times*, 12 March 2001, <http://www.nytimes.com/2001/03/12/world/yale-pressed-to-help-cut-drug-costs-in-africa.html?scp=1&sq=March%2012.%202001%20Yale&st=cse/> (accessed May 25, 2010).

¹⁷⁵ Sell, *Private Power*, 157.

failure of infrastructure for the delivery of health care. The corporate coalition requested and was granted a six week recess to reconsider their approach.¹⁷⁶

During the recess, MSF and Oxfam began an online petition and sent open letters to organizations and individuals encouraging them to oppose the lawsuit. In about four weeks, MSF collected almost 300,000 signatures and support from about 140 organizations worldwide in their online campaign, “Drop the Case.”¹⁷⁷

Before the case returned to court in April 2001, the pharmaceutical companies withdrew their lawsuit. As a concession from the South African government, they received a guarantee that the government would respect WTO rules under the TRIPS Agreement.¹⁷⁸ However, the rules for the use of compulsory licensing and parallel importing remained unclear.

Brazil

Brazil recognizes health as “a right of all and a duty of the State” in its Constitution¹⁷⁹ and has fostered a strong domestic pharmaceutical industry through its statutory commitment to procure generic medicines for use in its public health system.¹⁸⁰ With the publicly funded provision of medicines to be estimated at 25% of national consumption, the use of generics has allowed the government to realize substantial savings in its bid to provide universal health care.¹⁸¹ This became even more crucial for treating HIV/AIDS.

¹⁷⁶ Olesen, 13-14.

¹⁷⁷ MSF-USA, “Alert: Campaign Update, Access to HIV/AIDS Medicines” (June 1, 2001), <http://doctorswithoutborders.org/publications/alert/article.cfm?id=3322&ref=tag-index> (accessed June 2, 2009).

¹⁷⁸ Olesen, 12-14.

¹⁷⁹ Article 196, Brazil Constitution, 1988.

¹⁸⁰ Jillian Clare Cohen and Kristina M. Lybecker, “AIDS Policy and Pharmaceutical Patents: Brazil’s Strategy to Safeguard Public Health,” *The World Economy* 28, no. 2 (February 2005): 215.

¹⁸¹ *Ibid.* Cohen and Lybecker also note on page 214 that in 2002, Brazil was ranked the 10th largest market for pharmaceuticals.

During the 1990s, Brazil had over 200,000 reported cases of HIV/AIDS among its population and with the assistance of the World Bank began an innovative plan of action, the National AIDS Program, to provide antiretroviral drugs at no charge for all who were affected.¹⁸² The success of this policy was due in part to Brazil's manufacturing capacity, which provided a strong incentive for pharmaceutical companies to provide patented drugs at a reasonable price or risk their manufacture under compulsory license. Local production of ARV drugs already accounted for almost half of the medicines used in the program.¹⁸³

In addition, Brazil's *Industrial Property Law*, 1996, required patent holders to manufacture their product in Brazil within three years of patenting and made provision for compulsory licensing to be granted when a patent was not worked in Brazil for three consecutive years. The law also allowed for parallel importation if patent holders produced their product elsewhere. In the case of pharmaceuticals, Brazil argued that the threat of compulsory licensing had persuasively kept the cost of antiretroviral drugs under control and within the government's economic means.¹⁸⁴

Merck was a key supplier of ARVs and the Pharmaceutical Research and Manufacturers of America asked the USTR to oppose Brazil's law at the WTO. The company claimed that importing its drugs into Brazil was the equivalent of working the patent and compulsory licensing should be disallowed.¹⁸⁵ In 2000, the United States filed a case against Brazil requesting consultation with the Dispute Settlement Body. The U.S. charged that the wording of the *Industrial Property Law*, Article 68, with regard to

¹⁸² 't Hoen, "TRIPS," 44-45. Also Sell, *Private Power*, 136-137.

¹⁸³ Cohen and Lybecker, 217.

¹⁸⁴ 't Hoen, "TRIPS," 44-45. Also Sell, *Private Power*, 136-137.

¹⁸⁵ Sell, *Private Power*, 137.

compulsory licensing was inconsistent with the TRIPS Agreement and was discriminatory towards U.S. patent holders.¹⁸⁶

Non-governmental organizations in Brazil and international NGO's including MSF, rallied against the U.S. challenge to Brazilian law. Brazil's treatment program of universal access to ARVs had been successful in decreasing by half the mortality rate from AIDS related illnesses and in providing an improved quality of life for survivors.¹⁸⁷ MSF issued a press release that warned that U.S. action would interfere with the program and dissuade other states from seeking assistance from Brazil.¹⁸⁸

In addition, Brazil was very active with international organizations that were focusing on drug policy, including the World Health Assembly (WHA)¹⁸⁹ and the "TRIPS" Council at the WTO. At the WHA meeting in May 2001, Brazil was instrumental in linking human rights to the access of medicines, promoting an international monitoring system for drug prices, and gaining recognition for the use of generics as a valid strategy to combat HIV/AIDS, in spite of strong opposition by the U.S.¹⁹⁰ At the same time, developing states had approached the "TRIPS" Council to clarify that they could use the flexibilities in the agreement to protect public health without fear of sanction. During a meeting of the "TRIPS" Council in June 2001, a delegation from Brazil made a presentation about the success of their program and offered the necessary transfer of technology for developing states to build their own manufacturing capacity. This offer

¹⁸⁶ WTO, "Dispute Settlement: DS199, Brazil - Measures Affecting Patent Protection," http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm (accessed October 6, 2010).

¹⁸⁷ Sell, *Private Power*, 137.

¹⁸⁸ MSF, "Press Release: U.S. Action at WTO Threatens Brazil's Successful AIDS Program," 1 February 2001, <http://doctorswithoutborders.org/press/release.cfm?id=652> (accessed June 14, 2009).

¹⁸⁹ The WHA is the member organization that guides the World Health Organization.

¹⁹⁰ A. Nunn, E. Da Fonseca and S. Gruskin, "Changing global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil," *Global Public Health* 4, no.2 (March 2009): 137-141, http://www.hsph.harvard.edu/faculty/sofia-gruskin/files/Nunn_et_al_GPH.pdf (accessed April 25, 2010).

was further supported by NGOs such as MSF who offered technical assistance to the governments.¹⁹¹

In July 2001, the U.S. government, subject to intense public pressure, announced that it would withdraw its complaint against Brazil, noting that Brazil had not actually used the law. The U.S. indicated that it would continue discussions with Brazil should the need arise to invoke a compulsory license in the future.¹⁹² The two states issued a joint submission to the WTO, posted on the website that the dispute had been resolved with a “Mutually Agreed Solution.”¹⁹³

A month later, Brazil issued a compulsory license to produce a drug under patent after negotiations with Hoffmann-La Roche seemed unsatisfactory, however an agreement was reached and the license ultimately abandoned.¹⁹⁴ The threat of compulsory licensing was widely persuasive; Merck also significantly lowered prices on two of its ARVs.¹⁹⁵

The cases involving South Africa and Brazil were instrumental in re-opening discussion on the meaning and implications of the TRIPS Agreement for public health policy at the WTO Ministerial Conference in November 2001.

Declaration on the TRIPS Agreement and Public Health

Few developing countries had attempted to engage the flexibilities contained in the TRIPS Agreement, but it was evident that the interpretation of the provisions was still contested by both pharmaceutical companies and developed states. The non-

¹⁹¹ Sell, *Private Power*, 158

¹⁹² Sell, *Private Power*, 158.

¹⁹³ WTO, “Brazil – Measures Affecting Patent Protection, Mutually Agreed Solution,” http://docsonline.wto.org/GEN_highLightParent.asp?qu=%28+%40meta%5FSymbol+IP%FCD%FC%2A%29+&doc=D%3A%2FDDFDOCUMENTS%2FT%2FIP%2FD%2F23A1%2EDOC%2EHTM&curdoc=22&popTitle=G%2FL%2F454%3Cbr%3EIP%2FD%2F23%2FAdd%2E1%3Cbr%3EWT%2FDS199%2F4 (accessed October 6, 2010).

¹⁹⁴ Cohen and Lybecker, 213.

¹⁹⁵ Ibid., 220.

governmental coalition that included MSF and the outcry from developing countries forced public health interests onto the agenda at the WTO Ministerial Conference in Doha, Qatar in November 2001.

A couple of months prior to the Doha meeting, the African Group of states, supported by NGOs from the access coalition, made a proposal for a ministerial declaration supporting public health when applying the TRIPS Agreement, and the document that was developed at the Conference was initiated by this proposal. It attempted to address three overarching concerns including “the nature and scope of the flexibility in the TRIPS Agreement” and “whether this flexibility would be interpreted by the WTO and its members in a broad, pro-public-health way.”¹⁹⁶ The third concern was whether states could use these mechanisms without the threat of coercive measures from WTO members and the pharmaceutical industry.¹⁹⁷

The Pharmaceutical Researchers and Manufacturers Association responded that patents were not relevant to access and that the larger problem was a result of poverty and the lack of government investment in health and supporting infrastructure. MSF and the access coalition countered this claim, acknowledging that while poverty and infrastructure were factors, patents were the primary cause of high drug prices and patents prevented generic access to cheaper medicines.¹⁹⁸

The issue was further advanced when just weeks before the Doha meeting, some deaths occurred in the US due to anthrax spores in mail. Canadian health officials threatened to invoke compulsory licensing to manufacture generic supplies of Bayer’s

¹⁹⁶ WTO, “TRIPS: TRIPS and Public Health,”

http://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm (accessed October 6, 2010).

¹⁹⁷ Ibid.

¹⁹⁸ Sell, *Private Power*, 159

ciproflaxin. Members of the U.S. Congress also briefly considered it. Faced with the possibility, Bayer agreed to lower its prices,¹⁹⁹ and it was obvious that Canada had successfully employed the same tactics used by Brazil to access less expensive ARVs.

When the Doha negotiations were underway, the African Group, Brazil and India led the coalition that sought a legally binding revision to the TRIPS Agreement, while the U.S. and Switzerland remained opposed.²⁰⁰ The result of the WTO negotiations was the Doha Declaration, adopted by 142 member states that confirmed the need to consider public health over commercial interests and that sought to clarify and reaffirm the rules already in the TRIPS Agreement.²⁰¹

The Doha Declaration on the TRIPS Agreement and Public Health is set out in seven paragraphs. It acknowledges the severity of the problems facing developing countries afflicted by high infection rates of HIV/AIDS, tuberculosis and malaria and states that the TRIPS Agreement should be part of the solution.²⁰² It confirms the need for the protection of intellectual property for continuing research and development but acknowledges the effect this may have on the cost of medicines.²⁰³ It states that the TRIPS Agreement “does not and should not prevent Members from taking measures to protect public health”²⁰⁴ and that they may use the flexibilities to their full extent. The Declaration reiterates the right of individual states to define national emergency and to determine the grounds to grant compulsory licenses.²⁰⁵ In addition, the Declaration

¹⁹⁹ Ibid., 160.

²⁰⁰ Ibid.

²⁰¹ Ellen ‘t Hoen, “Patents, Prices and Patients,” *UN Chronicle* No. 2 (2003): 13.

²⁰² WTO, “Doha WTO Ministerial 2001: Declaration on the TRIPS Agreement and Public Health,” Paragraph 1, 2, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed October 6, 2010).

²⁰³ Ibid., Paragraph 3.

²⁰⁴ Ibid., Paragraph 4.

²⁰⁵ Ibid., Paragraph 5.

extended the timeline for the least-developed states to become “TRIPS” compliant in the area of pharmaceuticals to January 1, 2016.²⁰⁶

Finally, the Declaration recognized in Paragraph 6 that there were some unresolved issues because the flexibilities were of no value to member states without manufacturing capacity. As noted by Correa, capacity requires technical expertise, equipment and compounds not easily acquired in developing states.²⁰⁷ Therefore states wanting to acquire a necessary drug and states agreeing to manufacture the drug would both have to grant a compulsory license, however, the exporting state would still be in violation of the TRIPS Agreement because Article 31(f) limits the license to production for the domestic market. The Council for “TRIPS” was directed to provide alternatives to the General Council by the end of 2002.²⁰⁸ It was not until August 2003 before an agreement about Paragraph 6 was reached.

Decision on implementation of paragraph 6, Section 31(f) of the Doha Declaration on the TRIPS Agreement and Public Health

As in past negotiations for IP protection, the United States and European Union initially presented a position weighted in favour of industry interests. The African Group and other developing countries drew a great deal of support from a very vocal coalition of NGO’s and generic drug manufacturers and therefore produced a stronger negotiating front than in past meetings.²⁰⁹

²⁰⁶ Ibid., Paragraph 7.

²⁰⁷ Carlos M. Correa, “Intellectual Property Rights and Inequalities in Health Outcomes,” in *Global Health Governance: Crisis, Institutions and Political Economy*, ed. Adrian Kay and Owain David Williams (UK: Palgrave MacMillan, 2009), 275.

²⁰⁸ WTO, “Doha,” Paragraph 6.

²⁰⁹ Duncan Matthews, “WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?” *Journal of International Economic Law* 7 no.1 (2004): 83-84

The debate among WTO members focused on identifying a list of diseases and medicines to be included in the exception to Article 31(f). Moreover, there was a need to agree on which countries could use the exception to import, and which countries would be allowed to produce generic drugs for export. In addition, safeguards were needed to protect the patented drug industry and to discourage re-exportation of the generic drugs to a third party, so rules were needed that would force exporting states to clearly identify generic drugs under compulsory license by their unique labeling, packaging and physical characteristics.²¹⁰

The African Group was opposed to the restricted list of illnesses as proposed by the U.S., which included only HIV/AIDS, tuberculosis and malaria, and was also opposed to restricting compulsory licensing privileges to only the least developed, rather than to all who were without manufacturing capacity. Disagreement also arose over which countries would be allowed to manufacture and export the medicines and over the added economic burden of special packaging and product identifiers such as pill colour, markings and shape.²¹¹

In the end, member states agreed to a temporary waiver of Article 31(f) of the TRIPS Agreement. Rather than list specific drugs, the waiver granted to importing states more autonomy to determine what measures should be included on a case by case basis by covering all patented pharmaceutical products necessary to alleviate a public health problem. The use of the waiver for importing generics was made available to the least developed countries and any others lacking appropriate manufacturing capacity in a

²¹⁰ Ibid., 92. See also Wolfgang Hein, "Global health Governance and WTO/TRIPS: Conflicts Between 'Global Market-Creation' and 'Global Social Rights,'" in *Global Health Governance and the Fight Against HIV/AIDS*, ed. Wolfgang Hein, Sonja Bartsch and Lars Kohlmorgen (UK: Palgrave MacMillan, 2007), 54-55.

²¹¹ Matthews, 86-88. Hein, 55.

health emergency. In addition, it was agreed that all WTO members could be exporters, but when utilizing the waiver, there was a duty by exporters to use special packaging or identifiers to discourage trade diversion from the intended recipient state.²¹²

The waiver also requires that permission from the patent holder be sought before issuing a compulsory license. In addition, to avoid duplicate payments to patent holders, only the exporting country would be responsible to provide adequate remuneration, and both importing and exporting states were required to disclose on a dedicated WTO website the quantity to be manufactured and identifying characteristics of the medicines to be supplied. While the exporting country had to ensure that the product under compulsory license went only to the recipient state as disclosed, lesser developed countries were permitted to form a regional trading block (where at least half of the states are considered least developed) to utilize economies of scale for buying larger quantities of needed drugs.²¹³

Although the waiver was considered a win for developing states, the Access coalition that was monitoring the negotiations was critical. A statement signed by fourteen NGO's called it "a 'gift' bound tightly in red tape" that contained complicated and ambiguous conditions for its use.²¹⁴ Some of the conditions would make use of the waiver both time-consuming and expensive. An example cited by Correa is the requirement to negotiate with the patent holder, and the need for a generic supplier to get a compulsory

²¹² Matthews, 95-96.

²¹³ WTO, "General Council: Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health," http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed April 18, 2008).

²¹⁴ MSF, "Joint NGO statement on TRIPS and public health WTO deal on medicines: a 'gift' bound in red tape," September 2003, http://www.msfaccess.org/media-room/press-releases/press-release-detail/index.html/%3Ftx_ttnews%5Btt_news%5D=66&cHash=218eafbc81 (accessed April 25, 2010).

license in both the importing and exporting state before submitting a bid to manufacture, an expense he argues that few companies would risk without a contract of sale.²¹⁵

Recent Outcomes Stemming from the Implementation of Paragraph 6

The Article 31(f) waiver is still in effect but in 2005 the WTO Council proposed that it be incorporated into a permanent amendment to the TRIPS Agreement. Member states initially had until December 2007 for two thirds of the 151 members to ratify acceptance, however, when this became clearly unattainable, the deadline was extended to December 2009. A couple of weeks before the deadline, the “TRIPS” Council again extended the deadline, and it is now set for December 31, 2011. By the end of September 2010, only thirty states plus the European Union had formalized their support for the amendment.²¹⁶

A second outcome from Paragraph 6 stems from the need for states with manufacturing capacity to put in place the necessary domestic legislation and regulatory framework to allow for the export of pharmaceuticals under compulsory license. Only Canada, Norway, India, the Netherlands, Iceland and the European Union have passed legislation for this purpose.²¹⁷

Use of the waiver has been limited to one case; in July 2007, Rwanda was the first to announce that it would invoke the waiver to import a fixed-dose combination HIV/AIDS drug from Canada. Canada posted its intention to supply the drug under compulsory license in October 2007 and the medicines were manufactured by Apotex Inc., Canada’s

²¹⁵ Correa, “Intellectual Property Rights and Inequities,” 277.

²¹⁶ WTO, “TRIPS and Public Health: Members accepting amendment of the TRIPS agreement,” http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed October 3, 2010).

²¹⁷ Correa, “Intellectual Property Rights and Inequalities,” 277. See also WTO, “Fact Sheet: TRIPS and Pharmaceutical Patents, Obligations and Exceptions,” http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#importing (accessed April 18, 2008).

largest pharmaceutical company.²¹⁸ Although Apotex met the commitment in September 2008 and September 2009, the company has been critical of the process, citing regulatory complications and excessive administrative costs, and has urged the Canadian government to amend the legislation allowing for exportation.²¹⁹

Next Chapter

The role of non-governmental organizations in pursuing access to medicines was instrumental in forcing the issue back onto the international trade agenda for policy revision, impacting state preferences in the interpretation of intellectual property rules, and in reducing prices on patented drugs. In the next chapter, I will examine one of the key contributors to the access debate, Médecins Sans Frontières. I will argue that the success of MSF is due in part to the culture of the organization, the reputation it has earned, and the resources it has managed. In addition, I will argue that the Campaign for Access to Essential Medicines, a creation of MSF International, has evolved into an epistemic community of professionals that have been able to successfully navigate through the intellectual property rules, present evidence based opposition to the claims made by states and corporations, and to engage with multiple stakeholders to encourage innovation and cooperation for drug access in the developing world.

²¹⁸ WTO, "TRIPS and Public Health: Canada is first to notify compulsory license to export generic drug," http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm (accessed April 18, 2008).

²¹⁹ Apotex Inc., "CAMR Federal Law Needs to be Fixed if Life-Saving Drugs for Children are to be Developed," Press release, 14 May 2009, <http://www.apotex.com/global/about/press/20090514> (accessed April 25, 2010).

Chapter 3

Médecins Sans Frontières is an international humanitarian medical aid organization dedicated to providing assistance to persons “whose survival is threatened by violence, neglect or catastrophe.”²²⁰ During 2009, MSF was active in more than 60 states, and the organization has grown to include sections in nineteen countries with an international office located in Geneva. In addition to setting up emergency medical aid missions, MSF maintains the Campaign for Access to Essential Medicines and is a founding member of the Drugs for Neglected Diseases *initiative*.²²¹ In 1999, MSF was the recipient of the Nobel Peace Prize.

From the beginning, MSF used a bold new approach for a non-governmental organization, and earned a reputation among other agencies and governments for engaging in unilateral action and unusual risk-taking. Frequently working in regions where other agencies would not operate, MSF would withdraw its volunteers only when absolutely necessary for their safety. Last to leave, MSF would typically be the first to return when the situation was more secure.²²²

Implicitly, MSF’s charter challenged traditional notions of sovereignty and assumed the right to intervene to relieve suffering and preserve human dignity. Using extensive media coverage and web-based forums, MSF publicly confronts what it perceives as injustice. Several factors have influenced the adoption of MSF’s underlying principles and assumptions, contributing to the culture and success of the organization.

²²⁰ MSF, “About Us. History and Principles,” <http://www.doctorswithoutborders.org/aboutus/?ref=main-menu> (accessed January 10, 2010).

²²¹ MSF International, www.mfs.org (accessed July 5, 2006).

²²² Dan Bortolotti, *Hope in Hell: Inside the World of Doctors Without Borders* (Canada: Firefly Books, 2004), 61.

The Founding of Médecins Sans Frontières

MSF was founded in 1971 by a group of French doctors and journalists led by Bernard Kouchner and Raymond Borel. Each of the founding groups contributed to MSF's underlying humanitarian principles based on their experiences in the field.

A small group of young doctors, including Bernard Kouchner, were serving as emergency aid physicians for the International Committee of the Red Cross (ICRC) in 1968 during the Biafran-Nigerian crisis. Kouchner and his colleagues believed that their humanitarian efforts were being undermined by the political actions of the Nigerian government. Government troops trying to stop the secessionist movement and flush out the rebel leaders had surrounded the Biafran territory preventing delivery of goods. The ICRC and UNICEF had negotiated with the government for supplies to be delivered equally to both sides of the conflict, but food aid quickly dwindled when the Nigerian government withdrew its permission for airlifts into the Biafran region. Kouchner and his colleagues were outraged because in their view the government was complicit in the starvation of the Biafran people.²²³

The ICRC policy of neutrality and confidentiality does not permit its volunteers to engage in public criticism of parties involved in a conflict because the organization has always been dependent on the goodwill and consent of governments to engage in aid efforts. Kouchner and other witnesses to the Biafran crisis rejected this policy, and upon their return to France sought out and granted interviews to the media. Kouchner has

²²³ Tim Allen and David Styan, "A Right to Interfere? Bernard Kouchner and the New Humanitarianism," *Journal of International Development* 12 (2000): 829.

defended this action stating that, “By keeping silent, we doctors were accomplices in the systematic massacre of a population.”²²⁴

As international media interest grew in the Biafran crisis, the televised images of starving children created intense public pressure on humanitarian agencies to intervene. In response, Oxfam, the ICRC, and other NGO’s resumed unauthorized air shipments of food and supplies into the Biafran region; estimates suggest that as many as 7800 relief flights occurred before the conflict ended in 1970.²²⁵ Kouchner and his associates were participants in this initiative. Having abandoned the constraints of the ICRC, they had formed a new organization, the International Committee Against Genocide in Biafra, and were responsible for launching at least three aid missions in 1969.²²⁶

After the Biafran conflict ended, it became apparent that the Nigerian government was not solely responsible for the food shortages. Rebel leaders were accused of having strategically blocked supplies and of using the images of starving people to garner support for their cause through the Western media.²²⁷ In light of this information, evidence suggested that the unauthorized humanitarian action may have extended the crisis for eighteen months contributing to prolonged suffering and casualties of some 180,000 people.²²⁸ Most NGOs regretted their participation in unauthorized intervention and returned to the policy of respecting sovereign borders until invited in. However,

²²⁴ Ibid., 830.

²²⁵ Ibid.

²²⁶ Ibid.

²²⁷ James Orbinski, “Global Health, Social Movements and Governance,” in *Governing Global Health: Challenge, Response, Innovation*, ed. Andrew F. Cooper, John J. Kirton and Ted Schrecker (England: Ashgate Publishing, 2007), 70.

²²⁸ Allen and Styan, 830.

Kouchner and his group were not deterred by the controversy, and their experience greatly influenced the philosophical underpinnings of MSF, formed a year later.²²⁹

The second founding member, Raymond Borel, also contributed to the underlying principles of MSF. Borel was a physician and was the editor of a medical journal in France. The journal encouraged French physicians to volunteer their skills to assist in several natural disasters, and Borel had started a relief agency, Secours Medical Francais. In 1970, they volunteered to assist in Eastern Pakistan after a devastating cyclone that claimed about 500,000 lives. Borel and his group, along with other aid agencies, waited for some time for the Pakistani government's permission to enter their territory to assist in relief efforts. Frustrated by the constraints placed on humanitarian action, Borel sought to achieve a faster response time for the delivery of medical aid in natural disasters. In 1971, his group joined with Kouchner under the banner of MSF.²³⁰

The Culture of Médecins Sans Frontières

Médecins Sans Frontières was based on a founding charter and mission statement that declared that it would be an international humanitarian agency that would respond to medical emergencies arising from both natural and man-made disasters. The charter declared that MSF respected the right of all people to receive humanitarian assistance, impartially and ethically delivered by its medical personnel and vowed to treat the victims "irrespective of race, religion, creed or political affiliation."²³¹ MSF recognized the need to remain "independent from political, economic and religious powers"²³² in

²²⁹ Ibid.

²³⁰ Bortolotti, 46. Also Orbinski, *An Imperfect Offering*, 68.

²³¹ MSF-Canada, www.mfs.ca (accessed July 5, 2006).

²³² Orbinski, "Global Health," 68.

order to maintain its neutrality and independence. Over time, the mission statement has evolved to include victims of “armed conflict, epidemics and healthcare exclusion.”²³³

Tong has argued that non-governmental organizations that are active in relief work are quite diverse in how they perceive humanitarianism, and she suggests that their differences can be better understood by examining four basic features that influence their responses including the organization’s tradition, typology, political and cultural heritage, and mandate for action.²³⁴ Tong notes that the organizing principles of neutrality, impartiality and independence from religious and political structures were entrenched in the MSF charter from the beginning and are consistent in the tradition promoted by Henri Dunant, founder of the ICRC. These principles are considered to be the basis of classical humanitarianism and tend to be adopted by organizations that specialize in projects involving shorter term commitments, such as emergency relief operations. In general, classical humanitarian NGOs can usually exercise more autonomy, tend to receive a larger portion of their funding from private sources and operate on a more defined mandate.²³⁵ This seems to aptly describe the tradition of MSF, which guards its independence from other powers, consistently raises more than 80% of its overall funding from the private sector, and has kept a selective operational mandate in the area of health.

In locating the typology of MSF among non-governmental organizations, Tong draws on a model by O’Malley and Dijkzel based on a vertical and horizontal axis. In their model, the vertical axis has as its opposing points “total independence from religious and

²³³ MSF International, <http://www.msf.org/> (accessed December 18, 2009).

²³⁴ Jacqui Tong, “Questionable Accountability: MSF and Sphere in 2003,” *Disasters* 28, no.2 (2004): 177.

²³⁵ *Ibid.*, 177-178. Tong contrasts classical humanitarianism with Wilsonian and faith based NGOs.

political powers” to “a willingness to accept public service contracts.”²³⁶ The bisecting horizontal axis represents a continuum from “the willingness to deliver aid impartially according only to need” through “delivery based on the identity or affiliation of a particular group.” Tong suggests that MSF’s typology lies in the outermost sector where the value of total independence converges with that of complete impartiality. She argues that, for MSF, “independence is viewed as a necessary condition to be able to deliver humanitarian assistance in an impartial manner.”²³⁷

Cultural differences may also contribute to the relationship that NGO’s have with governments. Tong argues that Anglo-Saxon organizations are more likely to engage in collaborative and participatory relationships with political powers whereas those with Latin roots, like the French MSF, tend to adopt adversarial roles. Tong notes that political life in Europe has been characterized by “a mixture of evolution and revolution”²³⁸ which has been used as a catalyst to promote change in the power structure of the system. She argues that MSF fits within this pattern because it attempts to effect change (revolution) by speaking out and drawing attention to the victims, but continues to work within the system in an effort to assist in the transitions (evolution) brought about by political processes.²³⁹

The revolution Tong is referring to is the controversial practice of *témoignage*. Based on his experience with the ICRC policy of silence, Kouchner intended that volunteers working under Médecins Sans Frontières would practice *témoignage*, the act of

²³⁶ The model is found in A. Stoddard, “Humanitarian NGOs: Challenges and Trends,” *HPG Report on Humanitarian Action and the Global War on Terror: A Review of Trends and Issues* (London: Overseas Development Institute, 2003).

²³⁷ Tong, 179.

²³⁸ *Ibid.*, 178.

²³⁹ *Ibid.*, 178-179.

“witnessing and speaking out”²⁴⁰ to the media and other audiences. He hoped to draw widespread attention to the plight of those needing assistance and to those who were victims of human injustice. Borel, however, was opposed to this action fearing that governments would prohibit the group rather than risk ridicule hence the original Charter explicitly said MSF would “refrain from making judgement or expressing public opinions.”²⁴¹ It was not for several years, and after Kouchner’s departure from the organization, that the important concept of *témoignage* became an intrinsic part of MSF culture.²⁴² *Témoignage*, often defined in the MSF literature as raising awareness, is now considered to be the second function that MSF performs after providing medical assistance and is recognized in the Annual Activity Report as a justified expense with its own line in the budget.²⁴³ Although it was praised by the Nobel Prize Committee, there have been cases where the practice has resulted in MSF being expelled by a government.²⁴⁴ Yet speaking out is defended by MSF as necessary to engage civil society and for its continued autonomy and solidarity with the victims. When appropriate, it can serve to highlight root causes of injustice and put pressure on persons, governments or institutions that should be held accountable. Tong notes that although the practice is sometimes perceived as advocacy of human rights or lobbying, *témoignage* would be more accurately defined as a testimonial based on what is actually seen and experienced by the MSF volunteers. Recognizing that their expulsion from a territory could result in patients receiving no health care, MSF uses speaking out as a last resort.

²⁴⁰ Ibid., 181.

²⁴¹ Bortolotti, 47.

²⁴² Ibid., 46-56.

²⁴³ MSF, “The Annual Activity Report,” <http://www.msf.org> (accessed Feb 13, 2010).

²⁴⁴ In 1985, MSF was expelled from Ethiopia for speaking out against the government for worsening conditions during a famine. As one of the few NGOs ever admitted into North Korea, it was expelled in 1998 for criticizing the government’s diversion of aid. Recently in 2009, two sections of MSF were expelled from Darfur.

It is usually employed when it has become apparent that humanitarian assistance has reached its limits of effectiveness or when aid has become a catalyst for further violence in the region.²⁴⁵

The politics in France in the 1960s and 1970s also had an enduring effect on the cultural identity of MSF. Taithe argues that MSF was created in the aftermath of the student revolution in France, when the atmosphere was characterized by militancy and group solidarity. By the mid-1970s, political events in East Asia and Eastern Europe had begun to erode European support for Marxist ideology, and this trend was evident among the intellectuals based in the Latin Quarter in Paris. Kouchner, a charismatic speaker and familiar personality from his involvement in the student revolution, was able to garner support from the political Left by promoting an image that appealed to existentialist ideology. Kouchner insisted that outcomes could be altered by intervening in human tragedies and that “individual emotive responses rather than institutional ones”²⁴⁶ were what was needed. Referring specifically to Biafra, he claimed that the original intervention was launched by just a few doctors and characterized their stand as one of “free agents against institutions”.²⁴⁷ Many influential academics and media personalities were persuaded and supported Kouchner in the formative years of MSF, contributing to key principles such as the sense of solidarity with the victims because it captured the French “existentialist notion of ‘*engagement*.’”²⁴⁸

Another French influence that may have contributed to the culture of MSF provides the basis for the notion of quick intervention. From its inception, MSF sought to obtain a

²⁴⁵ Tong, 181.

²⁴⁶ Bertrand Taithe, “Reinventing (French) universalism: religion, humanitarianism and the ‘French doctors,’” *Modern and Contemporary France* 12, no.2 (2004):149.

²⁴⁷ *Ibid.*, 149.

²⁴⁸ *Ibid.*

rapid deployment to get to the victims and Taithe argues that this is derived from the “original notion of ‘*urgence*.’”²⁴⁹ Taithe explains that French medical aid movements in the late 1950s and 1960s developed national emergency response services that would bring the physician and medical team to the site of an accident in order to avoid time lost while transporting the injured to a waiting hospital-based team. This proactive form of medical intervention that underscored the importance of getting to the victim quickly was adopted by MSF in the early years. Small teams of volunteers made up of medical personnel and journalists would be deployed to a crisis along with a few supplies, and teams frequently had to wait for the appropriate tools to arrive before any relief could occur. However, this was consistent with Kouchner’s assertion that simply being there in solidarity with the victims affirmed human dignity and could promote change.

Tong notes that some organizations adopt multiple mandates providing both short term relief and long term development, but she argues that through most of its history MSF has been a single mandate organization focused on providing medical relief. MSF maintains universal ethical standards in its delivery of medical aid²⁵⁰ and insists on unhindered access to the victims. MSF is selective in its missions and will likely choose not to participate in those it perceives as politicized. In recent years violence against aid workers has increased and MSF has lobbied against the blurring distinction between militarized and humanitarian aid. As stated by Orbinski in his Nobel speech, the “moral intention of the humanitarian act must be confronted with its actual result.”²⁵¹ Because of the humanitarian failures in the 1990s in Somalia and Rwanda, MSF has become more

²⁴⁹ Ibid., 151.

²⁵⁰ Tong, 180. She lists these as beneficence (to do good), non-maleficence (to not do harm), autonomy (informed consent, privacy and confidentiality) and justice.

²⁵¹ James Orbinski, Nobel Prize acceptance speech, http://nobelprize.org/nobel_prizes/peace/laureates/1999/msf-lecture.html (accessed January 10, 2010).

introspective in evaluating its actions and has occasionally withdrawn its services when it determined that the provision of aid had unintended consequences such as fuelling more violence or was diverted for other uses.²⁵²

From its inception, MSF expected governmental cooperation in obtaining access to populations in need and the freedom to carry out their duties without political interference. Considered somewhat radical at the time, MSF's assumptions about intervention were rooted in the French language. While unauthorized intervention was generally considered a challenge to sovereignty and was not regarded by states as legitimate, Allen and Styan suggest that in France humanitarian intervention was "technically legal."²⁵³ The phrase used to signify the right to intervene is *le droit d'ingérence*, and because *droit* can also denote 'law' they argue that there may be an implied meaning of a 'law to intervene'. Furthermore, Allen and Styan argue that the French media frequently used *le devoir d'ingérence* or 'duty to intervene' which may infer the existence of a moral obligation to intervene for humanitarian reasons.²⁵⁴

Similarly, DeChaine argues that MSF's conception of *sans frontières* was based on this implied duty or right to intervene. He links their expectation to be allowed to transcend traditional state borders to their conception of humanitarianism as a universal rights-based activity that stands apart from the constraints of political space.²⁵⁵ For the French doctors, the justification for humanitarian intervention *sans frontières* was based on a moral imperative toward other humans to relieve their suffering, and was not a political act to be subject to the constraints of defined territories. Although the right for

²⁵² Tong, 180.

²⁵³ Ibid., 830.

²⁵⁴ Ibid., 828.

²⁵⁵ D. Robert DeChaine, *Global Humanitarianism: NGOs and the Crafting of Community* (US: Lexington Books, 2005), 91-92.

humanitarian intervention is still contested, the idea of facilitating access to populations became more accepted by the late 1980s. The need for neutral corridors was recognized due to the increasing number of joint operations by NGOs and the United Nations to provide basic necessities in the midst of conflicts and natural disasters. Although not legally binding, the United Nations General Assembly eventually passed resolutions that affirmed the importance of the work of humanitarian groups and that recognized the need for ensuring relief corridors for the distribution of aid.²⁵⁶

Organizational Structure and Missions

Initially, MSF drew its unpaid volunteers from the medical community and the media. Small medical teams were formed in haste to respond to crisis situations, and journalists were recruited for the missions for the purpose of “dramatizing the situation and the role of MSF doctors.”²⁵⁷ The French media were responsive to publicizing the events, and the international media soon took an interest in MSF’s activities. Television proved to be an effective medium to use the frames of human suffering and need for immediate action, and the reputation of the “heroic doctors” grew faster than their capacity to engage in missions.²⁵⁸

From the beginning, an ideological cleavage had developed between core members about the goals and capacity of MSF. Some were uncomfortable with what critics have called “commodifying tragedy.”²⁵⁹ Many wanted to undertake a more professional approach to the delivery of aid and add logisticians and administrators to the team. The

²⁵⁶ Allen and Styan, 831-832. UN General Assembly Resolution 43/131 passed in 1988 is available at <http://www.un.org/documents/ga/res/43/a43r131.htm> and Resolution 45/100 passed in 1990 is at <http://www.un.org/documents/ga/res/45/a45r100.htm>

²⁵⁷ Kevin McDonald, *Global Movements: Action and Culture* (UK: Blackwell, 2006), 76.

²⁵⁸ Taithe, 151. Also McDonald, 76.

²⁵⁹ McDonald, 76.

changing nature of conflicts brought the opportunity to engage in longer term humanitarian commitments, and the need for stable funding was becoming more pressing. MSF became more bureaucratic in organization and more democratic in its decision making about missions. Kouchner was alarmed at the transition and argued that MSF was forgetting that its mandate was to be rooted in emotive response. Finding himself in the minority, Kouchner and a few of the originals left MSF in 1979 and formed a similar NGO, Médecins du Monde.²⁶⁰

According to Bortolloni, Kouchner's departure allowed MSF to professionalize and begin fundraising in earnest, but the group also pursued more radical practices including witnessing and speaking out. Within months, MSF breached its pledge of neutrality and illegally entered Afghanistan to provide medical aid to the Afghan resistance after the Soviet invasion, and they staged a mediatised protest against the Khmer Rouge in Cambodia. This pattern continued and earned MSF a reputation as a "brash and fearless group that went where others would not go,"²⁶¹ causing MSF's popularity to spread throughout Europe. Between 1980 and 1985, four additional sections of MSF opened in Belgium, Switzerland, Holland and Spain, and an office linked to Belgium opened in Luxembourg. In 1990-91, MSF expanded to the United States and Canada, followed by several more chapters and offices throughout the world, totaling 29 national offices by 2009.²⁶²

MSF's missions had also expanded to include different forms of health emergencies. Many governments in developing countries were unable to provide for basic health needs, often as a result of structural adjustment programs and declining health care

²⁶⁰ Taithe, 150-151. Also Bortolloni, 52-54.

²⁶¹ Bortolloni, 55-56.

²⁶² MSF, www.msf.org/. Also Bortolloni, 63.

funding. In many cases, there was no infrastructure for the administration of health care and non-governmental organizations were stepping up to assist communities in longer-term projects for their survival. For MSF, emergency medical assistance would shift to also include combating outbreaks of disease, providing mass vaccinations, and distribution of drugs and other medical supplies. Nutrition, shelter, safe water supplies and proper sanitation were intrinsically linked to improved health and were included in the humanitarian mandate. Education for prevention of illness, pre- and post-natal care for mothers and infants, and collecting information on ongoing health problems such as tropical and emerging illnesses increasingly became the role of those on the ground. MSF became active in working with health officials in less developed countries to set up and maintain more accessible clinics for communities in rural areas, and in training local health care providers who could continue the project upon MSF's withdrawal.²⁶³

A second factor that expanded the mandate of emergency aid was the increase in the number of civil wars. Emergency medical care was required for the growing number of affected populations, and included refugees and displaced persons.²⁶⁴ McDonald notes that the transformation from war between states to conflict within states meant that the traditional model for emergency medical relief could not be supported. Wars were no longer fought by armies in a designated territory; rather, civil wars were usually situated in populated areas and the casualties were predominantly civilian. Combatants were often rebel factions and ethnic groups, and the tools of war included terrorizing

²⁶³ Mike Toole, "Frontline Medicine: The Role of International Medical Groups in Emergency Relief," in *World in Crisis: The politics of survival at the end of the twentieth century*, ed. Médecins Sans Frontières (UK: Routledge, 1997). Also, Lisa Fuller, "Justified Commitments? Considering Resource Allocation and Fairness in Médecins Sans Frontières-Holland," *Developing World Bioethics* 6, no.2 (2006): 61. (online)

²⁶⁴ Bortolotti, 50-51.

communities, ethnic cleansing, and genocide. Affected states lacked the capacity to provide for their people and the stability of neighbouring states was often threatened by migration. Caring for the injured and displaced populations of civil wars had been gradually taken over by humanitarian organizations.²⁶⁵

The growth of MSF into a global organization and the changing dimension of health needs demanded a more formalized organizational structure, and permanent staff was needed. Modest salaries were paid to those in the field to cover their expenses, and MSF was able to hire and train local caregivers and non-medical staff in many of the locales where they serve. By 2002, the combined budget was about US\$400 million, and MSF employed about 15,000 national staff and 3,000 expatriates for positions in the fields of medicine, logistics and administration.²⁶⁶ This had grown to 27,000 staff by 2008.²⁶⁷

To provide coordination for the growing organization, the International Council was formed in 1991 with a representative from each section on the council, and MSF International opened permanent offices in Geneva ten years later. The five European based sections of MSF have maintained responsibility for the operational side of the missions and accept larger amounts of funding from government sources. The remaining thirteen sections are partnered with a European office and primarily perform the functions of recruitment, fund raising, public education and public relations although the U.S. has recently participated in joint operations with its partner, France.²⁶⁸

²⁶⁵ McDonald, 75.

²⁶⁶ Bortolotti, 27. He also notes on page 65 that over half of the expats are from the 5 European states in charge of operations. Almost 60% of the staff is medically trained.

²⁶⁷ MSF-USA, "Annual Report 2008," 28, <http://www.doctorswithoutborders.org/donate/policy.cfm> (accessed February 13, 2010).

²⁶⁸ Bortolotti, 63. It should not be assumed that the sections are fully homogenous in culture or goals. Nor should it be assumed that the sections coordinate their missions. Each has unique features and undertakes missions as it perceives a need and the capacity to offer service, and at times, more than one section could be operating autonomously in a given state.

In keeping with the goal to retain its political independence, MSF has consistently raised more than 80% of its overall annual funding through donations from the private sector.²⁶⁹ MSF-USA is the largest fundraiser and in 2008, raised \$151 million which was about 20% of the overall budget. Of this amount, 84.5% was from private individuals, 12% from foundations and only 3.5% was from corporate donations.²⁷⁰ MSF-USA does not accept any funds from the government, and it maintains a conflict of interest policy that prohibits donations from corporations and foundations that profit from substances that may contribute to poor health or that may be related to concerns addressed by MSF, including tobacco, arms, extractive industries, and pharmaceuticals.²⁷¹

MSF and the Issue of Access to Pharmaceuticals

Non-governmental organizations concerned with health and poverty issues, along with many of the lesser-developed and developing countries, began to contest the implications and effects of intellectual property rights for pharmaceuticals soon after the TRIPS Agreement came into force. One of the major catalysts for their concern was the ever increasing number of infections of HIV/AIDS among the populations in developing countries and the lack of access by the poor to the vastly improved antiretroviral medicines that were being developed.

During the late 1980s and early 1990s, the global health focus had turned towards HIV/AIDS. Most large pharmaceutical companies were heavily invested in the research and development of drugs to manage the virus and the often lethal complications that arose from it. In 1996, shortly after the TRIPS Agreement came into effect, an announcement was made at the XI International AIDS Conference in Vancouver that the

²⁶⁹ Bortolotti, 66. In recent years, the Annual Reports show this figure to be as high as 89.9%.

²⁷⁰ MSF-USA, "Annual Report," 42.

²⁷¹ Ibid.

new combined triple antiretroviral therapies would “convert deadly AIDS into a chronic, manageable disorder like diabetes.”²⁷² But for the patients served by MSF in the developing world, the new ARV treatments were not available.

The numbers of people infected with HIV in lower income countries had spiraled uncontrollably and most suffered from complications due to other tropical diseases to which they had become even more susceptible. Unlike the demographics for those affected by HIV in the western world, the prevalence of the virus was almost equally divided between males and females, and mother-to-child transmission at birth was occurring at an alarming rate. In 1999, it was estimated that 16 million had already died of AIDS and another 33 million people worldwide were infected with HIV; of those infected, 26 million (80%) were living in Sub-Saharan Africa with no access to treatment. Although two million Africans died from AIDS that year, less than 1% of the market share of antiretroviral drugs was sold to African states. The cost of the new HIV drugs was well beyond the reach of poor governments at more than \$10,000 per person for a year’s supply of the patented medicines.²⁷³

For MSF, the HIV/AIDS epidemic was only part of the burden of disease that threatened their patients in low income countries. Infectious and parasitic diseases including malaria, tuberculosis, African sleeping sickness and Chagas disease in Latin America were causing enormous suffering and contributed to about 25% of the overall disease burden in the developing world. Estimates in 1999 showed that communicable diseases were responsible for the death of about 14 million people, mostly in lower

²⁷² Orbinski, “Global Health,” 34.

²⁷³ Nathan Ford and Daniel Berman, “Essential Medicines and Compulsory Licensing,” in *HAI-LIGHTS* 3, no.1 (1999), Health Action International, <http://www.haiweb.org/pubs/hailights/may99.html> (accessed April 17, 2008).

income countries. Again disproportionately, the developing world consisted of 80% of the global population, but only accounted for 20% of the market share for pharmaceuticals.²⁷⁴ In light of this, MSF leaders turned their attention to finding ways to cope with the diseases that ravaged the populations they were working within.

Driven by the desire to learn why their patients' pharmaceutical needs were largely ignored, MSF formed its own "internal research capacity" to scrutinize the policies that contributed to the issue of neglected diseases.²⁷⁵ What MSF concluded was that while several diseases most prevalent among their patients could be treated by drugs, the issue of access was complicated and had multiple barriers.

First, the newer medicines were protected under patent for twenty years and brand names were far too expensive; newer drugs for tuberculosis, for example, exceeded \$15,000 per course of treatment.²⁷⁶ With the implementation of the TRIPS Agreement, access to generic brands was becoming more difficult, and the remaining suppliers of generics were in developing countries including India and Brazil and were initially expected to comply with "TRIPS" rules as of 2000, then 2005 after the Doha Declaration.²⁷⁷

Second, having worked in the field, MSF knew that many older versions of drugs were fraught with management problems such as storage temperature, complicated dosages and drug combinations, as well as dangerous side effects. Many existing drugs had become ineffective due to increased drug resistance, as was prevalent with multi-drug resistant tuberculosis. Some medicines, including ARVs, were formulated for adult

²⁷⁴ MSF, *Fatal Imbalance: the Crisis in Research and Development for Drugs for Neglected Diseases* (Geneva: MSF, 2001): 8-11.

²⁷⁵ Orbinski, "Global Health," 34.

²⁷⁶ MSF, *Fatal Imbalance*, 11.

²⁷⁷ TRIPS agreement

patients, or in the case of Chagas, were only useful to treat children. Yet, MSF learned that only 13 of the 1,393 new drugs approved between 1975 and 1999 were indicated for tropical diseases and 3 were for tuberculosis.²⁷⁸ Moreover, diseases that affected the developing world were clearly not a priority since nine of the thirteen new drugs that had been developed resulted either from contracts with the U.S. government to treat Vietnam veterans or from veterinary research primarily indicated for livestock.²⁷⁹

A third factor limiting access was that in some cases drugs that had been effective were no longer deemed profitable for the manufacturers and production had ceased. In addition, with the exception of the new anti-retroviral treatments, most ongoing research and development by pharmaceutical corporations was not indicated for diseases that were prevalent in the developing world.²⁸⁰ According to The Global Forum for Health Research, the leading burdens of disease in 1999 were lower respiratory infections, diarrheal and perinatal conditions; however, of the US\$50-60 billion invested annually by the public and private sectors for research and development, only 10% was directed towards the conditions affecting 90% of the global population.²⁸¹

Based on its findings, MSF's strategy to improve access to medicines included engaging several actors in pharmaceutical policy using advocacy, collaboration and evidence-based opposition. MSF connected with governments, international and non-governmental organizations, pharmaceutical companies and researchers to work toward a

²⁷⁸ Patrice Trouiller, Piero Olliaro, Els Torreele, James Orbinski, Richard Laing and Nathan Ford, "Drug Development for Neglected Diseases: a Deficient Market and a Public-Health Policy Failure," *Lancet* 359 no. 9324 (June 2002): 2189, <http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673602090967.pdf?id=3d35b1b5aa0ec416-47766f9:12836060eeb:-135b1272220098862> (accessed April 25, 2010).

²⁷⁹ MSF, *Fatal Imbalance*, 11.

²⁸⁰ MSF, *Fatal Imbalance*, 11.

²⁸¹ Global Forum for Health Research, *The 10/90 Report on Health Research*, [online], <http://www.globalforumhealth.org/Media-Publications/Publications/10-90-Report-on-Health-Research-1999> (accessed April 25, 2010).

solution. They sponsored conferences on the access issue, produced educational materials highlighting the problems, counseled government officials on the flexibilities within the TRIPS Agreement, and lobbied for change.

Access to Essential Medicines Campaign

The financial boost that MSF needed to institutionalize its goal for access to pharmaceuticals came in the form of the Nobel Peace Prize in 1999. The Nobel Committee selected MSF in recognition of its international humanitarian service and focus on human rights, and the presentation speech highlighted the core values contained in the MSF Charter including independence, impartiality, and speaking out.²⁸² A portion of the more than US\$1 million prize money was allocated by MSF to build on its new research initiative and to formally launch the “Access to Essential Medicines Campaign”.²⁸³

The Campaign’s international office was opened in Geneva; strategically, this location was important for several reasons. First, Geneva is the home of many international organizations that are focused on trade such as the WTO, WIPO, and UNCTAD. It is also home to health-based organizations including World Health Organization and UNAIDS, as well as being the European base for the United Nations and UNHCHR. In addition, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has its head office here. Hein refers to this as the “Geneva connection” and argues that it is a “microcosm of the whole complex of interfaces” that

²⁸² Nobel Prize Foundation, “Nobel Peace Prize 1999, Award Ceremony Speech,” 10 December 1999, http://nobelprize.org/nobel_prizes/peace/laureates/1999/presentation-speech.html (accessed November 17, 2009).

²⁸³ Bortolotti, 161.

occur in global health governance.²⁸⁴ He notes that while major differences exist in the functions of the many organizations based in Geneva, a common thread underlies their interactions through respect for human rights norms and all are affected by global health concerns. Hein describes close ties within the ‘Geneva connection’ that result from both formal and informal networking through participation in a variety of workshops and events, and through personal and private contacts. In addition, Hein cites job mobility between international and non-governmental organizations to be a significant factor in “intensifying communication between different organizations.”²⁸⁵

Initially there were four key personnel who formed the nexus of the MSF campaign: the head of MSF France, Dr. Bernard Pécoul, Ellen ‘t Hoen who was a trade lawyer and had worked with Health Action International and WHO on drug policy, former pharmaceutical marketing executive, Daniel Berman, and the MSF International President, Dr. James Orbinski, a Canadian physician with extensive field experience.²⁸⁶

According to Orbinski, the Access Campaign was “rooted in a social justice ethic” for the benefit of their patients who continued to suffer from treatable infectious diseases.²⁸⁷ The primary goal was to achieve “equitable access to proven effective treatments”²⁸⁸ for people in lower income states. The campaign was focused on three areas: to overcome the barriers that prevented access, to encourage innovation in research and development for neglected diseases, and ultimately to influence international trade agreements to be more responsive to public health concerns. In the short term, MSF sought more

²⁸⁴ Hein, 59.

²⁸⁵ Ibid., 61.

²⁸⁶ Orbinski, “*An Imperfect Offering*,” 354.

²⁸⁷ Orbinski, “Global Health,” 34.

²⁸⁸ Ellen ‘t Hoen, “Dying of market failure,” *International Journal of Risk and Safety in Medicine* 13 (2000): 137.

affordable drugs through persuading patent holders to engage in differential, equitable pricing based on parity²⁸⁹ and promoted the use of compulsory licensing and parallel importing by states without capacity to provide for their own health needs, as well as the use of Bolar provisions for generic manufacturers to fast track approvals for the production of medicines coming off patent.²⁹⁰

Advocacy and Education

The formal MSF Campaign was built on its ongoing participation in the wider transnational access network and coalition. Although MSF had not traditionally been reputed to collaborate with other NGOs, Pécoul, the Director of the French MSF, joined the transnational access network initiated by Health Action International and CP Tech in 1998. The network had rapidly expanded, and CP Tech was host to an extensive online “listserv” for intellectual property and health, which was instrumental in the dissemination of ‘dense webs’ of information to the network that was forming around the world.²⁹¹ The addition of the MSF Campaign further aided in the development of a larger transnational advocacy network of more than a hundred non-governmental organizations and civil society groups, and the base funding allowed MSF to send volunteers to work with domestic health and policy NGO’s in many countries.²⁹²

As part of the access coalition, MSF was active in organizing and convening conferences and workshops focused on drug access. In May 1998, the World Health

²⁸⁹ MSF has drawn a distinction between using terms for discounted drug pricing such as differential or tiered, arguing that these do not necessarily translate into equitable and affordable for a given population, hence purchasing power parity must be considered for fair access. See ‘t Hoen, Ellen, Suerie Moon and B Pécoul, “Pills and pocketbooks: Equity pricing of essential medicines in developing countries,” http://data.unaids.org/Publications/IRC-pub05/pills-pocketbooks_en.pdf (accessed April 23, 2010).

²⁹⁰ ‘t Hoen, “Dying of market failure,” 137. For information on the Bolar exception, see WTO Fact Sheet: TRIPS and Pharmaceutical Patents, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#bolar (accessed April 24, 2010).

²⁹¹ CP Tech listserv archives are available at <http://lists.essential.org/pipermail/ip-health/>

²⁹² Orbinski, *Imperfect Offering*, 354.

Assembly had tabled a proposal for a Revised Drug Strategy that would formalize the role of the WHO in monitoring the effects of “TRIPS” and other trade agreements on drug access. The revision also included that part of the WHO’s mandate would be to provide assistance to governments in ensuring the primacy of public health over trade.²⁹³ The opposition put forth by the U.S. and other industrialized states provided a political opportunity for the NGOs to host a series of meetings with negotiators to educate them about IP rules and constraints on health policy. A year later, the 191 state members of the WHA unanimously passed Resolution 52.19, and the NGOs released a statement that this was a first step toward improving health. Implementation, however, would be the key.²⁹⁴

For the NGO coalition, part of implementation would mean understanding the legal flexibilities in the TRIPS Agreement and how lower income states might utilize them. Among the first international projects for the MSF Campaign was co-convening a conference in Geneva with HAI and CP Tech for about 120 delegates from 30 countries to explore the practical implications of compulsory licensing for developing countries.²⁹⁵ This conference was followed up a few months later by another in the Netherlands with 350 participants from 50 countries, including representatives from national governments, industry and several intergovernmental institutions, including the World Bank and World

²⁹³ WHO, “Revised Drug Strategy,” 27 January 1998, http://apps.who.int/gb/archive/pdf_files/EB101/pdfangl/angr24.pdf (accessed April 17, 2008).

²⁹⁴ MSF, HAI and CP Tech, “Joint Release on WHA Revised Drug Strategy,” 25 May 1999, <http://lists.essential.org/pharm-policy/msg00095.html> (accessed April 17, 2008). See also Sell, *Private Power*, 147-149.

²⁹⁵ A summary of the conference is available at MSF, “AIDS and essential medicines and compulsory licensing” (March 25–27, 1999), http://www.msfacecess.org/resources/key-publications/key-publication-detail/index.html%3Ftx_ttnews%5Btt_news%5D=1297&cHash=7827c3de8f (accessed October 6, 2010).

Health Organization.²⁹⁶ At the conclusion of the conference the NGO organizers issued a formal declaration, the *Amsterdam Statement to WTO Member States on Access to Medicine*. The Statement, released just prior to the Seattle WTO Ministerial Meeting in November 1999, called for the creation of a standing working group to advise the WTO Council for “TRIPS” and “to consider the impact of trade policies on people in developing and least developed countries, and provide a public health framework for the interpretation of key features of WTO agreements.”²⁹⁷ Among the policy alternatives they wanted considered was the use of compulsory licensing, relaxing the administrative rules for generic production, and new incentives for innovative research and development. Disappointed with the responses from some attending the conference, representatives from HAI, CP Tech and MSF also lobbied the U.S., E.U. and WHO prior to the WTO meeting, and went to Seattle to urge member states to “recognize that public health takes priority over trade.”²⁹⁸ Although Orbinski suggests their efforts in Seattle were a failure,²⁹⁹ it was at this meeting, coinciding with World AIDS Day, that Clinton announced the USTR would change its approach to health and trade policy to ensure “that people in the poorest countries won’t have to go without medicine they so desperately need.”³⁰⁰

MSF also worked with the World Health Organization and the Rockefeller Foundation to organize an October 1999 conference in Paris for the health industry that included

²⁹⁶ As Sell and Prakash note on page 162, some international organizations had an instrumental reason to support the Access coalition. The World Bank for example purchased approximately US\$800 million in pharmaceuticals annually.

²⁹⁷ CP Tech, “Amsterdam Statement to WTO Member States on Access,” <http://www.cptech.org/ip/health/amsterdamstatement.html> (accessed April 17, 2008).

²⁹⁸ Ellen ‘t Hoen, “Doctors in Seattle: The battle for access to essential drugs,” *Development* 43, no.2 (2000): 101-104.

²⁹⁹ Orbinski, *Imperfect Offering*, 357.

³⁰⁰ William Clinton, “US President Clinton’s speech to the WTO,” 1 December 1999, http://www.pbs.org/newshour/bb/international/wto/clinton_wto_12-1.html (accessed February 14, 2010).

pharmaceutical companies and researchers, who with the growing access coalition explored the need for medicines for neglected diseases. The Drugs for Neglected Diseases Working Group evolved from this conference with the goal to “seek new and creative strategies”³⁰¹ for promoting research and development for neglected diseases. Chaired by Orbinski, some of the initial undertakings and feasibility studies were funded by MSF.³⁰² By 2003, four pilot projects had evolved, and MSF had formalized a relationship between five public sector groups, a research group and UNDP/World Bank/WHO’s Special Programme for Research and Training in Tropical Diseases to form the Drugs for Neglected Diseases *initiative* (DNDi).³⁰³ Their mandate was to challenge the traditional logic of research and development as being market-driven and profit-oriented, and to replace it with an alternate vision of a needs-based process that would respond to health priorities. As a not-for-profit venture, DNDi has continued to work to encourage, locate and combine research and development resources, particularly in the area of neglected diseases, which can be pooled to meet health needs and to assist governments in building local capacity. The initial projection was to register six to eight new drugs through this project by 2014.³⁰⁴ DNDi has successfully coordinated three new drug treatments and is overseeing several more currently in the development process.³⁰⁵

The consultations between non-governmental and governmental organizations, states and pharmaceutical corporations resulted in a plethora of conferences and workshops aimed at educating stakeholders, resolving access issues and finding innovative solutions

³⁰¹ MSF, *Fatal Imbalance*, 4.

³⁰² MSF, *Fatal Imbalance*, 4.

³⁰³ DNDi. www.dndi.org (accessed April 14, 2008).

³⁰⁴ MSF. “Members’ Briefing on Infectious Diseases in the Developing World,” Speech by Nicolas de Torrente, Executive Director of MSF-USA to the US Joint Congressional Caucus of Human Rights and Congressional Black Caucus Health Brain Trust, May 15, 2003.

<http://www.doctorswithoutborders.org/publications/article.cfm?id=1332> (accessed February 14, 2010).

³⁰⁵ DNDi, “Diseases and Projects,” <http://www.dndi.org/diseases.html> (accessed February 14, 2010).

for universal access to essential medicines. Initially sponsored primarily by MSF and other health NGOs,³⁰⁶ part of this role, particularly in the area of HIV/AIDS, was assumed by international institutions beginning in 2001. Although UNAIDS was established in 1996, it had limited success on its own in setting and reaching objectives.³⁰⁷ When WHO began a more concerted effort for HIV/AIDS beginning in 2001, the two organizations, often in concert with World Bank, focused on reversing the trend of increasing numbers of HIV/AIDS infections in the developing world and in lowering mortality rates.³⁰⁸ With increased leadership at the international level, the access coalition and MSF remained active as presenters and participants in the forums,³⁰⁹ but were also able to channel their resources into an expanded campaign for neglected diseases.

Through the Access to Essential Medicines Campaign, MSF has also lobbied and worked with intergovernmental organizations to create a better understanding of access needs. MSF has maintained observer status at the World Health Assembly meetings and is active in promoting its concerns to the European Commission, influencing E.U. advocacy of access issues. Through its work with the World Health Organization, MSF has lobbied for and succeeded at getting newer medicines onto the WHO List of Essential Medicines and was instrumental in pressuring WHO to create a Commission on

³⁰⁶ For example, MSF and HAI sponsored a conference for 21 East African countries on patents and pricing in June 2000,

³⁰⁷ UNAIDS did have some minimal success in negotiating with 5 drug companies for the Accelerating Access Initiative, however, the actual output of cheaper drugs was slow in coming and limited in scope.

³⁰⁸ Lars Kohlmorgen, "International Governmental Organizations and Global Health Governance: the Role of the World Health Organization, World Bank and UNAIDS," in *Global Health Governance and the Fight Against HIV/AIDS*, ed. Wolfgang Hein, Sonja Bartsch and Lars Kohlmorgen (UK: Palgrave MacMillan, 2007), 130.

³⁰⁹ An example is Ellen 't Hoen's presentation on equity pricing at the WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs in Norway, April 2001, http://www.wto.org/english/tratop_e/TRIPs_e/hosbjor_presentations_e/hosbjor_presentations_e.htm (accessed April 24, 2010).

Innovation. The findings of the Commission are frequently cited by MSF in its arguments for better health outcomes. And as early as 2000, MSF, UNAIDS, UNICEF and WHO worked together to research and produce a drug selection and pricing guide for HIV/AIDS treatment.

MSF is also one of five hundred civil society signatories to the *Geneva Declaration on the Future of the WIPO* (2004), which supported the movement for the creation of a development agenda at WIPO.³¹⁰ On several occasions MSF has addressed WIPO meetings urging it to conduct an impact assessment before proceeding with IP reforms, to provide technical assistance to developing countries trying to use “TRIPS” flexibilities, and to consider new models to encourage innovation and transfer of related technology and knowledge.³¹¹

MSF’s role in the fight for universal access has also been acknowledged by international governmental organizations. In December 2003, UNAIDS and WHO announced the launch of their “3 x 5 initiative” to get 3 million infected persons in the developing world onto ARV therapy by the end of 2005. In the press release, the program is described as a “complement” to ongoing efforts including “the pathfinding work of NGO’s (like MSF).”³¹²

Relationship with Pharmaceutical Corporations

Transnational pharmaceutical corporations have maintained that patents are necessary to reward innovation and encourage re-investment in research and development.

³¹⁰ CP Tech, “Geneva Declaration on the Future of the WIPO,”

<http://www.cptech.org/ip/wipo/futureofwipodeclaration.pdf> (accessed April 22, 2010).

³¹¹ Statement by MSF at the WIPO General Assembly meeting Sept. 2004 and at the Inter-Sessional Intergovernmental Meeting on a development agenda, April 11-13, 2005, <http://www.who.int/intellectualproperty/topics/ip/MSF%20statement%20at%20WIPO%20GA%20%2030%20%20Sep%20%202004.pdf> (accessed April 24, 2010).

³¹² UNAIDS, WHO. “Plan to get 3 million AIDS patients on treatment by 2005,” http://data.unaids.org/Cosponsors/WHO/pr_who_3by5_01dec03_en.pdf (accessed April 22, 2010).

Research costs are high, and it takes years to develop a new product which can, without the protection of patents, be inexpensively copied by generic manufacturers who do not share the burden of research costs. Major drug companies argue that compulsory licensing and other “TRIPS” flexibilities will only harm future patients by discouraging innovation and private sector investment. In addition, drug companies have blamed access issues in developing countries on poor or non-existent health care systems, tariffs, pilfering and mark-ups within national boundaries, and the lack of competent health care professionals needed to administer and supervise complex treatment programs.

MSF has claimed that in principle it is not against patents for inventions, however, in the case of drugs which can save lives and end suffering, patents should not limit access and artificially raise prices beyond the reach of governments.³¹³ Also, MSF has challenged the use of patents to extend a monopoly over a drug past the initial 20 year life by re-registering it for new indications or with slightly changed chemical properties or combinations, a commonly used technique known as ‘evergreening.’ MSF has argued that to meet the criteria for a patent, a product must be both new and inventive, which is consistent with WTO expectations.³¹⁴ As for discouraging research, the counter-position offered by MSF and others has been that pharmaceutical research and development is focused on diseases of the North and has little bearing on the drugs needed for neglected diseases in developing countries. Early in the campaign, it was shown that 80% of the drug market share was in North America, Europe and Japan, which represented

³¹³ MSF, “The impact of patents on access to medicines,” <http://www.msfaccess.org/main/access-patents/introduction-to-access-and-patents/the-impact-of-patents-on-access-to-medicines/> (accessed April 24, 2010).

³¹⁴ MSF, *Drug patents under the spotlight: sharing practical knowledge about pharmaceutical patents*, (Geneva: MSF, May 2003), 6-7, 12-13. For the “TRIPS” definition of criteria for patentability, see WTO, “Fact Sheet: and Pharmaceutical Patents, Obligations and Exceptions,” Article 27.1, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (accessed April 24, 2010).

disproportionately only 20% of the global population. Moreover, the coalition argued that research costs were greatly exaggerated by drug companies and that transparency was needed to determine realistic costs.³¹⁵ Further inquiry has shown that many drugs were developed or partially funded within publicly funded institutions such as state sponsored laboratories and universities before being licensed to drug companies for manufacturing.³¹⁶ MSF and CP Tech argued for example that for fourteen HIV/AIDS drugs in production in the late 1990s, over half of the funding for clinical trials came from the U.S. government.³¹⁷

Pharmaceutical companies also argued that patients in resource-poor countries would not be able to develop and maintain the strict regime necessary for HIV treatment, especially when multiple combinations of drugs taken at different times daily was the treatment prescribed. MSF was able to draw on its experiences to refute the claim. In 2000, MSF set up its first HIV treatment project in Thailand and initiated similar programs in six countries the following year. A program jointly sponsored by MSF and the provincial health authority in the township of Khayelitsha, South Africa, showed that HIV treatment regimes, including limiting the risk of vertical transmission from mother to child, could be successfully managed if affordable drugs were made available.³¹⁸

³¹⁵ Ellen 't Hoen, "Access to Essential Drugs and Globalization," *Development* 42, no.4 (1999): 90. The author notes that the IFPMA has claimed that drug development could cost as much as US\$500 million in 1998 compared to the US tax office's claim of US\$2.3 million in 1994.

³¹⁶ Sell and Prakash, 163, report that Yale University jointly holds the patent on AIDS drug d4T produced by Bristol-Myers Squibb. During the Access campaign in 2000, Yale was asked to grant permission for generics to be manufactured. Yale students held protests in support of access and were instrumental in forcing the drug company to reduce the price dramatically for poor countries.

³¹⁷ 't Hoen, "Dying," 139. More recent estimates show that the public sector provides 44% and the private sector 48% of funding for research. For more on recent innovation in pharmaceutical research and development, see Carlos M. Correa, "Intellectual Property Rights and Inequalities," 266-269.

³¹⁸ Christian von Soest and Martin Weinel, "The Treatment Controversy: Global Health Governance and South Africa's Fight Against HIV/AIDS," in *Global Health Governance and the Fight Against HIV/AIDS*, ed. Wolfgang Hein, Sonja Bartsch and Lars Kohlmorgen (UK: Palgrave MacMillan, 2007): 217-218. Also, Orbinski, *An Imperfect Offering*, 359-363.

Concurrently, generic drug companies in Thailand, India and Brazil, where patents were not yet recognized for both product and processes, developed the capacity to manufacture antiretrovirals for HIV and had simplified the dosage regime by creating combined therapy drugs. MSF publicly announced it would purchase direct from generic manufacturer Cipla in India, and Cipla agreed to sell MSF its ARV “cocktail” for \$350, compared to the patented price of over \$10,000 per person for a year’s supply.³¹⁹ MSF publicly challenged brand name drug companies to match this price and offer it to lower income states.³²⁰ The actions of MSF and others in the coalition would eventually contribute to a lowering of prices for developing countries.

The MSF Access Campaign drew global attention in 2000 during the lawsuit against South Africa’s legislation allowing for compulsory licensing and parallel importing. South Africa, with an estimated 4 million people infected with HIV, was attempting to create domestic laws and regulations to use the flexibilities contained in the TRIPS Agreement. MSF joined with British-based Oxfam, CP Tech and a South African grassroots organization, Treatment Access Campaign (TAC), to publicize the case brought by 39 multinational pharmaceutical companies. The Access Campaign became a collaborative effort with CP Tech lobbying the US government, and Oxfam publicly shaming pharmaceutical companies Glaxo and Pfizer. MSF specifically targeted Pfizer for its refusal to lower prices and launched a publicity campaign against them in eighteen (mostly industrialized) countries. Their efforts brought tremendous public pressure on the companies by suggesting that corporate greed was taking precedence over public

³¹⁹ Sell and Prakash, 162.

³²⁰ MSF. “AIDS Triple-Therapy for Less than a \$1/Day,” 7 February 2001, [http://www.msfaccess.org/media-room/press-releases/press-release-detail/?tx_ttnews\[tt_news\]=107&cHash=ff1ecde155](http://www.msfaccess.org/media-room/press-releases/press-release-detail/?tx_ttnews[tt_news]=107&cHash=ff1ecde155) (accessed April 24, 2010).

health. When the companies finally dropped the suit against South Africa, many, including Glaxo, Merck, Abbott and Bristol-Myers Squibb, had also dropped prices for specific products or had agreed to begin donations of certain drugs to poor countries.³²¹

MSF also teamed up with South Africa's Treatment Action Campaign in 2002 to import Brazilian manufactured generic ARVs for its project in Khayelitsha.³²² This project had become central to TAC's position in the South African legal case, and had continued to be the focal point in pressuring the South African federal government to extend universal access to treatment. Drug companies were opposed to the action of importing generics, however, after the public relations disaster from the lawsuit the year before, the drug companies chose to merely observe.

Not all of the interactions between MSF and pharmaceutical corporations have been contentious. Drug companies have voluntarily entered into negotiations for the production of essential medicines and have offered some patents for free. MSF and WHO partnered in 1999 to gain access to drugs for neglected diseases and realized some early successes when the French company Aventis agreed to produce a medicine for sleeping sickness that had ceased production a few years earlier because it was not profitable. Similarly, MSF and WHO, through the Green Light initiative,³²³ negotiated substantial discounts in pricing with Eli Lilly for treatment of multidrug-resistant tuberculosis in 2000 and were able to oversee the rational use of the drugs in controlled

³²¹ Jordi Trullen and William B. Stevenson, "Strategy and Legitimacy: Pharmaceutical Companies' Reaction to the HIV Crisis," *Business and Society* 45, no.2 (June 2006): 187.

³²² MSF, "Joint Press Release MSF, TAC and Oxfam: Importation of Generics Cuts Price in Half," 29 January 2002, <http://www.doctorswithoutborders.org/press/release.cfm?id=547&cat=press-release> (accessed April 24, 2010).

³²³ WHO started the Green Light Committee initiative in 2000 to procure good quality, inexpensive drugs for use in managed programs for tuberculosis. See WHO, "The Green Light Committee Initiative," http://www.who.int/tb/challenges/mdr/greenlightcommittee/faq1_initiative/en/index.html (accessed April 24, 2010).

programs.³²⁴ Another success was reached in 2001 when MSF asked Yale for permission to access generics of its patented ARV drug d4T. Yale had exclusively licensed it to Bristol-Myers Squibb, and after pressure mounted from the student body and others, Bristol-Myers not only dramatically cut its prices but also offered the license to be used for free by other manufacturers.³²⁵

Other Strategies

MSF has been aggressive in its approach to challenging what it perceives as unjust or uninformed, and uses the media, the internet, and conference forums to publicly disagree with and challenge positions taken by international organizations such as World Health Organization, the WTO and WIPO.³²⁶ MSF is a frequent contributor to publications such as *The Lancet* and *UN Chronicle* where they urge states to address global concerns. An example of this is a challenge they presented in October 2006 to the Executive of WHO to select a new leader who would “assert its leadership in view of new independent actors that come with vast resources,” and critically asked if it would “continue to stifle dissenting voices from its staff, as it has done in the past?”³²⁷ While MSF criticizes, it also continues to work with these organizations, and with WHO in particular, to promote better health outcomes.

MSF has engaged in several online petitions that have been successful in generating thousands of signatures globally to assist in pressuring corporations and organizations on

³²⁴ Orbinski, “An Imperfect Offering,” 363.

³²⁵ MSF, “Access Campaign Accomplishments 1999-2002,” http://www.msf.org/msfinternational/invoke.cfm?component=article&method=full_html&objectid=4DA0AB2D-B77D-4304-B2D4AED326C4EA96 (accessed April 24, 2010).

³²⁶ Examples are WHO’s “Massive Effort” project that was criticized Oct. 4, 2000 for claiming that treatments exist and WHO needs to be more ambitious in its approach, MSF-USA, <http://www.doctorswithoutborders.org/press/release.cfm?id=636&cat=press-release/> (accessed July 25, 2010).

³²⁷ MSF, “Historic opportunity for WHO to re-assert leadership,” *The Lancet* 368 (Oct. 21, 2006): 1406, www.thelancet.com (accessed Oct. 8, 2009). For comment on leadership at the WHO, see Ingram, 87.

behalf of those in need of medicines. For example, MSF collected 420,000 signatures in 2007 through its online petition urging Novartis drug company not to pursue its case against India's patent laws.³²⁸ MSF also maintains an active internal research capacity to compliment its involvement in pursuing access to medicines for neglected diseases, and has conducted some trials among its patients in resource-poor settings to challenge notions that treatment cannot be managed without more advanced health systems in place.

MSF produces high quality brochures advocating medicines access and innovation in research that are widely distributed through conferences and workshops on health issues. MSF has also created several travelling poster displays for use in public venues, such as the Access to Essential Medicines EXPO based on "photographs, sound, text and interactions with MSF field volunteers"³²⁹ to raise public awareness. While many of the materials featuring their humanitarian work tend to focus on caring for people in need, the visual images created specifically for the access campaign are typically based in a social justice framework designed to highlight the inequality between the 10% who have access to drugs and the 90% who do not. It would seem likely that the former are designed to advertise good works and elicit financial donations, while the latter are directed toward emotive responses to encourage protests and outrage at the inequity of being able to pursue a basic human right to health.³³⁰

³²⁸ MSF. "Promoting Generic Competition," <http://www.accessmed-msf.org/main/hiv-aids/introduction-to-hivaids/promoting-generic-competition/> (accessed April 20, 2008).

³²⁹ MSF. "Members' Briefing on Infectious Diseases." In 2002, the travelling poster exhibit was used in the US for about a year going to 30 cities to bring awareness of neglected diseases. About 30,000 signatures were also collected urging the US government and pharmaceutical companies to devote new resources to research in this area.

³³⁰ Examples can be seen at MSF. "Three years of Access posters, 1999-2002," http://www.msf.org/msfinternational/invoke.cfm?objectid=3A936825-06B4-4565-9BC77C78D216E6EA&component=toolkit.article&method=full_html (accessed April 24, 2010).

In addition, MSF continues to put pressure on pharmaceutical companies and produces an annual edition of “Untangling the Web of Price Reductions: a pricing guide for the purchase of ARVs for developing countries.” First produced in 2001, the thirteenth edition was released in July 2010 and documents comparative information on differential pricing between pharmaceutical suppliers and the countries where the drugs are purchased. This has been instrumental in keeping prices down and more fairly accessed in developing countries.³³¹

MSF has also continued to perform a watchdog function, scrutinizing and publicly criticizing bilateral and regional trade agreements, particularly those that contain “TRIPS-plus” requirements and frequently addresses this concern on its website and through glossy publications. A 12 page brochure produced in August 2003 addressed the dangers to health that could occur if the Free Trade Area of the Americas agreement was signed with the U.S.³³² In 2004, MSF distributed a similar publication that warned all governments against entering into regional or bilateral trade agreements with the U.S. MSF charged that because the U.S. had been forced into concessions at the WTO with regard to IP protection, it was now pursuing the interests of its pharmaceutical corporations by including provisions that exceeded both the terms and spirit of the TRIPS Agreement. At that time, MSF listed seven agreements that had been concluded and several that were pending.³³³ More recently, in March 2010 MSF was calling on India to

³³¹ Available on the MSF website [http://www.msfaaccess.org/resources/key-publications/key-publication-detail/index.html?tx_ttnews\[tt_news\]=1631&cHash=1e60ab329f](http://www.msfaaccess.org/resources/key-publications/key-publication-detail/index.html?tx_ttnews[tt_news]=1631&cHash=1e60ab329f) (accessed August 16, 2010).

³³² MSF, “Trading Away Health: Intellectual Property and Access to Medicines in the Free Trade Area of the Americas (FTAA) Agreement,” http://www.doctorswithoutborders.org/publications/reports/2003/FTAA_Advocacy.pdf (accessed April 24, 2010).

³³³ MSF, “Access to Medicines at Risk Across the Globe: What to Watch for in Free Trade Agreements with the United States,” *Briefing Note*, May 2004, 1-12,

avoid entering into an agreement with the European Union that would result in restrictions on their generic industry's ability to produce much needed medicines for the developing world.³³⁴ MSF has also been active in advising governments when formulating legislation for importing and exporting of pharmaceuticals, and has been critical when governments include standards beyond the TRIPS Agreement.³³⁵

From the beginning of the Access Campaign, MSF has maintained that governments had the right to use the flexibilities under the TRIPS Agreement to protect public health goals. Orbinski argued that "civil society and the private sector cannot substitute for government, only government has a duty and a responsibility to provide for public goods."³³⁶ MSF recognized that this could not be achieved merely through donations of drugs or voluntary price reductions from benevolent pharmaceutical companies. In a study commissioned by the DND Working Group comparing the costs of drug access through models that included generic purchasing, donations, concessionary (buy some/get some free), discounted and differential pricing,³³⁷ it was found that governments could only be self-sufficient in meeting public health obligations through developing manufacturing capacity and using the legal means available in the TRIPS

http://www.doctorswithoutborders.org/publications/reports/2004/ftaa_05-2004.pdf (accessed April 24, 2010).

³³⁴ MSF, "Free Trade Agreements: What consequences for access to medicines?"

<http://www.msfaccess.org/main/access-patents/free-trade-agreements/> (accessed March 27, 2010). For more about US Free Trade Agreements and their TRIPS-plus requirements, see Correa, "Intellectual Property Rights and Inequalities," 277-280.

³³⁵ For example, MSF-Canada testified at the committee hearings for Bill C-9, and was critical of its exclusion of drugs that were not on the list of essential medicines.

³³⁶ James Orbinski, "Essential medicines for Neglected Diseases: Innovation and Access or 3 Civil Society Initiatives that Just might Matter..." speech given at the Conference of Montreal's CIDA/IDRC International Forum, "Diseases Without Borders: An Economic Struggle?" May 8, 2003 available from http://www.idrc.ca/en/ev-62094-201-1-DO_TOPIC.html (accessed August 16, 2005).

³³⁷ Alain Guilloux and Suerie Moon, "Hidden PriceTags: Disease-Specific Drug Donations: Costs and Alternatives," MSF/DND Working Group Feb. 2001: 189-210, http://www.deolhonaspatentes.org.br/media/file/Publicacoes/hidden_price_tags.pdf (accessed May 9, 2010).

Agreement. Although donations and reductions in pricing could be a temporary solution, this tended to create a disincentive to more affordable generic production, was restricted in availability, type of drug and use, and was frequently dependent on conditions that produced additional burdens on the recipient. MSF also argued that differential pricing based on affordability was useful in accessing some essential medicines such as vaccines; however, a more sustainable system would be needed to stimulate research and development, particularly for neglected diseases.³³⁸

Furthermore, financial donations to programs set up to assist in accessing medicines, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria³³⁹ and UNAIDS, were not as generous or forthcoming as had been anticipated. Bartsch has argued that funding targets set by the Global Fund were subject to competing interests such as economic shortfalls, renewed security concerns, and 'donor fatigue.' In addition, she notes that the Fund suffered from the diversion of resources to new programs such as PEPFAR.³⁴⁰ Finally, in some cases, financial donations were further constrained because of donor preferences where aid was limited to certain states or tied to specific types of programs, such as prevention, and other performance criteria that states were not always willing to surrender autonomy for.³⁴¹

Orbinski's concerns have been realized as newer second and third-line treatments have become available but are again offered under patent at a price that lower income states cannot afford. Currently, many patients in poor countries are receiving first-line

³³⁸ Ibid., 204-205.

³³⁹ The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria was launched in 2001 and is a public-private partnership between governments, civil society organizations and the private sector.

³⁴⁰ Sonja Bartsch, "The Global Fund to Fight AIDS, Tuberculosis and Malaria," in *Global Health Governance and the Fight Against HIV/AIDS*, ed. Wolfgang Hein, Sonja Bartsch and Lars Kohlmorgen (UK: Palgrave MacMillan, 2007), 159. PEPFAR, the US President's Emergency Plan for AIDS Relief, was launched in 2003.

³⁴¹ For a concise overview of funding problems for The Global Fund and PEPFAR, see Ingram, 91-96.

HIV/AIDS treatment that is less effective, toxic, or incompatible with other health issues, when they would benefit greatly by the newer more expensive regimes.³⁴²

MSF has continued to search for innovative solutions to the problem of access, particularly in the area of neglected diseases, and along with WHO was a proponent of the idea of a patent pool where drug companies and other research institutions could voluntarily submit their patents in exchange for royalties.³⁴³ Among the expected results of a pool would be lower prices and faster development of fixed-dose formulations by combining drugs from different originators. The pool is currently in the negotiation stage and is to be administered by UNITAID.³⁴⁴ In October 2009 MSF again used its website and the transnational advocacy network to pressure drug corporations to support the pool and launched an online “Make It Happen Campaign” which drew over 300,000 responses.³⁴⁵

Next Chapter

The next chapter will argue more specifically why MSF was crucial for the success of the access campaign. I will also examine the discursive mechanisms used by MSF and the coalition to frame and disseminate information, and show through a constructivist lens how discourse can be influential in changing state behavior. Finally, I will summarize my research and conclusions.

³⁴² MSF, “Untangling the Web of Antiretroviral Price Reductions,” http://utw.msfaccess.org/background/overcoming_challenges (accessed May 9, 2010).

³⁴³ A discussion and recommendation on patent pools is found in WHO, *Public health, innovation and intellectual property rights*, 52-53.

³⁴⁴ UNITAID is a project that has 29 member countries located mostly in Europe, South America and Africa. In 2008, 72% of the funding came from 7 of the countries who have instituted a tax on air travel to go toward the organization. The website is <http://www.unitaid.eu/en> See also MSF “Untangling the Web.”

³⁴⁵ MSF, “Make It Happen Campaign,” <http://www.msfaccess.org/main/access-patents/make-it-happen-campaign> (accessed Oct. 1, 2010).

Chapter 4

The transnational advocacy coalition and campaign played an important role in placing access to affordable medicines on the agendas of states, and in highlighting the problems associated with intellectual property rights harmonized within the patent regime under the TRIPS Agreement. As a member of the advocacy coalition, Médecins Sans Frontières played a seminal role by providing a leadership function and grafting its own formal campaign for increased drug access for HIV/AIDS and other neglected tropical diseases to that of the larger network. The leadership role assumed by MSF was crucial for this coalition and campaign to realize a measure of success for two important reasons. First, unlike other campaigns aimed at changing state norms, there was no leadership or mentorship from a developed state. Second, most rights campaigns have involved civil or political rights, whereas the right to health was an evolving social right and not widely recognized when the campaign began.

Campaigns and changing norms

Advocacy campaigns aimed at changing human rights norms have typically enjoyed substantial support from developed states. While non-state actors may be responsible for identifying issues and moving them onto the international agenda, successful outcomes have also been linked to the actions of states that champion the issue and provide a variety of tools to influence other states to adopt new norms. Two examples of state influence aimed at changing norms using a human rights lens include the diplomatic pressure and economic sanctions levied by powerful states against South Africa during the anti-apartheid campaign,³⁴⁶ and the leadership provided by Lloyd Axworthy and the Canadian government to advance the Ottawa Treaty during the International Campaign to

³⁴⁶ See David Black, "The long and winding road: International norms and domestic political change in South Africa," in *The Power of Human Rights: International Norms and Domestic Change*, ed. Thomas Risse, Stephen C. Ropp, and Kathryn Sikkink (UK: Cambridge University Press, 1999), 78-108.

Ban Landmines.³⁴⁷ In both cases, non-governmental organizations were the initial force behind the movement for change. However, in the first example, it was not until certain states joined the campaign that a shift in policy was considered by South Africa. Similarly, when a few key states put their support behind the landmines ban, a larger number of states quickly agreed to sign the treaty.³⁴⁸

The campaign for drug access differed in that it did not have support from any of the developed states and was in fact diametrically opposed to the more powerful states' preferences for strengthened intellectual property rights. Lower income and lesser developed states lacked the power to contest the position of wealthy states, and were only instrumental in resisting the claims of the pharmaceutical companies and negotiating for a change in the TRIPS Agreement at the WTO after the advocacy campaign provided educational and technical support through conferences, workshops and human resources. Without the support of any powerful state, the campaign required the leadership of a recognizable, credible and tenacious non-state actor as a necessary condition for the issue to progress. MSF had several attributes that allowed it to provide strong leadership for the access coalition.

The second consideration is that most successful advocacy campaigns have been directed at issues involving human rights that fall in the category of civil and political rights and have targeted governments or state policies that were seen as oppressive or

³⁴⁷ See Richard Price, "Reversing the Gun Sights: Transnational Civil Society Targets Land Mines," *International Organization* 52, no.3 (Summer 1998): 613-644. For a detailed account of state involvement in the landmines ban, see Motoko Mekata, "Building Partnerships toward a Common Goal: Experiences of the International Campaign to Ban Landmines," in *The Third Force: The Rise of Transnational Civil Society*, ed. Ann M. Florini (Tokyo: Japan Center for International Exchange and US: Carnegie Endowment for International Peace, 2000), 143-176.

³⁴⁸ Finnemore and Sikkink have described this phenomenon as the three stage "life cycle" of a norm: emergence, which ends in a tipping point, broad acceptance which includes a norm cascade, and finally, internalization in "International Norm Dynamics," 895-896.

arbitrary.³⁴⁹ The issue of medicines is more appropriately categorized as a social right encompassed within the right to health, and the target has included international agreements, corporations and individual government policies. Furthermore, rights enumerated in the International Covenant on Economic, Social and Cultural Rights have traditionally been viewed as secondary, and only in the last decade have gained widespread importance.³⁵⁰

The implications of a right to health are further complicated in that government involvement in the provision of health care has varied significantly between states. In most states several non-state actors participate in or have assumed responsibility for aspects of health policy and the delivery of services. National governments rely on the expertise of the private sector to conduct research, develop products, regulate ethics and standards of care, build facilities, and coordinate responses to emergencies, and this trend has intensified with the introduction of liberal economic policies.³⁵¹ Furthermore, few governments in the developing world have had the resources to manage even a small portion of health service delivery, especially for those who are living in remote areas or are marginalized due to the nature of their illness, and it has frequently been the mandate of faith-based and other non-profit organizations to assume this burden. Finally, understandings of health care and the needs of specific populations varies by state, culture and region, and the allocation of resources is bound up with competing interests within a state. As such, the right to health has remained largely aspirational.

³⁴⁹ This is evidenced in the case studies included in the edited books by Risse, Ropp and Sikkink (1999) and Keck and Sikkink (1998) such as women's rights, political prisoners and disappeared persons.

³⁵⁰ World Health Organization, "Human Rights, Health and Poverty Reduction Strategies," *Health and Human Rights Publications Series 5*, (2008), 1.
http://whqlibdoc.who.int/hq/2008/WHO_HR_PUB_08.05_eng.pdf (accessed July 25, 2010).

³⁵¹ Hans Löfgren, "The Competition State and the Private Control of Healthcare," in *Global Health Governance: Crisis, Institutions and Political Economy*, ed. Adrian Kay and Owain David Williams (UK: Palgrave Macmillan, 2009), 245-254.

Although international organizations including WHO and World Bank have been actively involved in researching and formulating health policy and in proposing state strategies for some time, they were frequently constrained by the preferences and base funding that came primarily from developed states. A breakthrough in recognizing a right to health came when the Millennium Development Goals (MDG) were adopted in 2000 by the United Nations General Assembly. The MDGs are directed at the eradication of poverty and include eight objectives, many of which are related to health. Most explicitly, Goal 6 is to “combat HIV/AIDS, malaria and other diseases” and as a target, expressly lists “universal access to treatment for HIV/AIDS for all that need it.”³⁵² Since their re-introduction through the lens of poverty reduction, social rights have gained more attention and acceptance by states. The launch of the MDGs presented a political opportunity for the health-based advocacy coalition to expand their base of supporters to include a wider range of NGOs that were focused on poverty, education and development issues, such as Oxfam and Third World Network.

The recognition of the obligations incumbent on all states to uphold a right to health was also more apparent as a result of the Millennium Goals. For MSF, this provided an additional political opportunity to press its agenda advocating innovative research and development, new global funding models and lowered drug prices. MSF had already been working on the drug issue with various governments, international organizations and other non-state actors through conferences and workshops. The adoption of the Millennium Goals was a good fit with the stated objectives of MSF’s formal Access

³⁵² United Nations Development Programme, “Goal 6: Combat HIV/AIDS, malaria and other diseases: Targets,” *Millennium Development Goals, Basic Facts, Goal 6*, <http://www.undp.org/mdg/goal6.shtml> (accessed July 25, 2010).

Campaign launched a year earlier, and allowed it to draw on rights-based language that was familiar to states when framing the issue.

Why MSF? - Filling the leadership void

MSF lacked the traditional power of a state and could not use diplomatic means or coercive economic sanctions states typically employ to pressure other states, but the organization had strengths that would allow it to fill the leadership void. MSF was internationally recognized for its expertise as a humanitarian medical organization and was able to use its extensive field experience and knowledge of treatment deficits to add credibility to the coalition's demands. MSF was also widely perceived by states and civil society as having legitimate authority and specialized knowledge in the area of health in resource-poor settings. MSF had national offices in most developed states, and had been active in more than 80 countries, and frequently provided services that governments were temporarily unable to manage. MSF had a very good reputation and its work was held in high esteem, as was evidenced when they were awarded the prestigious Nobel Peace Prize in 1999 for humanitarianism. Its depth of reach into the societies it served allowed MSF to represent the interests of a transnational constituency of stakeholders including those working in the area of health and those who were recipients of health care.

Adding to its efficacy was that throughout its history MSF had resisted state control of its mandate and projects by limiting its dependency on state funding and by maintaining decision-making ability over which missions it would embark on. The organization had guarded its autonomy by avoiding most types of development projects and collaborative missions in the field in order to operate according to its beliefs. MSF valued its identity as a principled and moral actor that sought to uphold the dignity of the individual, and the

organization embraced the use of *témoignage* when there was evidence of injustice. Staff and volunteers were able to voice their concerns and give witness publicly even when states were the target of their criticism.

The history and culture of MSF was embedded in such a way that during the access campaign, MSF openly challenged powerful states to re-evaluate the effects of the TRIPS Agreement and to meet their obligations to public health. MSF criticized international organizations such as WHO for weak policies and lack of leadership and publicly targeted the U.S. for its “TRIPS-plus” requirements in bilateral and multilateral trade agreements. This liberty would not have been possible for an organization that relied heavily on government funding and contracts, particularly from the U.S. government. Nor would it be possible for an organization such as the ICRC, which does not allow public comment from staff, and is reliant on goodwill and the cooperation of governments to continue its service delivery and monitoring function.

The breadth of MSF as a transnational organization also allowed for increased linkages and multiple access points to government officials and other non-state actors. Many of the national sections of MSF had prior ties to governments and international organizations through their participation at conferences and as frequent contributors to official inquiries about state foreign policy and humanitarian activity. The strategic location of the international office in Geneva was also an asset for creating formal and informal networks. It should be noted that there were other transnational organizations active in the campaign, such as Oxfam, who provided similar and complementary linkages with multiple state actors, and groups such as CP Tech that targeted their specific home states, and this strengthened the campaign significantly.

MSF was also able to form an epistemic community with expertise in both the health and legal aspects of the access issue. It had the internal capacity to decipher technical information about drugs and diseases and refute claims made by pharmaceutical corporations. This was in part because of their professional credentials and field experience, and partly because they were able to develop their own research capacity. Specifically, MSF's formal campaign greatly benefitted from the funds that came from the Nobel Prize. MSF allocated the 940,000 Euros awarded to them to create a fund for neglected diseases for research, testing and delivery of drugs, and to fund pilot projects in these areas.³⁵³ This is not to suggest that MSF alone provided technical support. Many campaign participants were immersed in treatment or policy research, generally at the domestic level. As well, HIV/AIDS activists and patient groups such as the South African TAC and generic drug companies provided solid evidence necessary for progress on the issue. Others such as Oxfam and CP Tech were proficient in providing legal support and other research capacities.³⁵⁴

As stated earlier in this paper, advocacy groups lack traditional power and must strategically use information and act as moral entrepreneurs in order to create influence. This requires a concerted effort to carefully frame messages for a targeted audience and the flexibility to seize upon political opportunities that arise. Using Keck and Sikkink's classification of information, symbolic, leverage and accountability politics,³⁵⁵ we can see that the coalition was very effective in framing and disseminating information.

³⁵³ MSF, "MSF Calls on Public Investment to Support Neglected Disease Research," *Press Release* (October 10, 2000), <http://www.doctorswithoutborders.org/press/release.cfm?id=637&cat=press-release> (accessed July 26, 2010)

³⁵⁴ Orbinski, "An Imperfect Offering," 359.

³⁵⁵ Keck and Sikkink, 16.

Framing the Issue and Disseminating Information

Framing issues and dissemination of information is a key function of a campaign. The definition of framing presented earlier in this paper was to define the issues and propose appropriate strategies for a specific audience. Similarly, Zald defines frames as “specific metaphors, symbolic representations and cognitive clues” that are used to define events and suggest alternative responses.³⁵⁶ Frames must resonate with the desired audience to suggest specific understandings of the issue and must be aligned to guide responsive behaviour.³⁵⁷

For constructivists who envision that state preferences are not fixed, discourse is an important tool in persuading states to adopt new behaviour. States are theorized as becoming socialized through their interactions with international actors and seeking legitimacy among other states. By re-conceptualizing a problem, frames may be effective in persuading actors that other perceptions are valid and legitimate, and can possibly lead to the development of new or changed norms.³⁵⁸

Information politics is crucial to building effective networks and coalitions, and MSF’s structure of national offices and volunteers in the field was beneficial for circulating information and drawing supporters. Factual information, updates on meetings, and position papers were quickly disseminated through MSF’s national websites and were also accessible to civil society and media outlets. Although CP Tech maintained a ‘listserv’ throughout, it detailed extensive and informal day-to-day communications better suited to organizers involved in the network and included other

³⁵⁶ M.N. Zald, “Culture, Ideology and Cultural Framing,” in *Comparative Perspectives on Social Movements*, ed. D. McAdams, J.D. McCarthy, and M.N. Zald (Cambridge: Cambridge University Press, 1996), 262.

³⁵⁷ Keck and Sikkink, 17.

³⁵⁸ Finnemore and Sikkink, “International Norm Dynamics,” 902-904.

topics affected by intellectual property rights. In contrast, MSF maintained dedicated campaign web pages which eventually became a permanent site for its formal campaign. It controlled its communications with carefully and consistently worded press releases and field reports that outlined new developments in the campaign, clearly re-iterated ongoing and new problems, proposed solutions for the ‘way forward’ and stated MSF’s position on the issue. The coalition also enjoyed a sympathetic media in developed countries, particularly during the South African lawsuit and when Cipla’s offer of inexpensive generics exposed the high pricing of brand name drugs.³⁵⁹

During the first two years of MSF’s Access Campaign, the official spokespersons were primarily Orbinski, Pécoul and ‘t Hoen, with comments by the presidents of MSF-USA and MSF-South Africa only in a couple of state specific cases. In each of the fifteen press releases studied, there was a perception of urgency and frequent use of MSF ‘calling on,’ ‘urging,’ and ‘demanding’ that governments, international organizations, or corporations perform a specific action. In their communiqués, MSF constantly reminded governments that it was the state’s responsibility to solve the issue of medicines that were priced too high or not even available and that states had a “right” to protect public health. A year into the campaign, MSF often incorporated into its statements that there was a ‘moral obligation’ to provide access to affordable drugs.³⁶⁰ Overall, the professionalism

³⁵⁹ Cipla’s offer was a front page headline, Donald G. McNeil Jr., “Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa, *New York Times*, 7 February 7 2001, <http://www.nytimes.com/2001/02/07/world/indian-company-offers-to-supply-aids-drugs-at-low-cost-in-africa.html> (accessed July 29, 2010).

³⁶⁰ My conclusions are based on my content analysis of fifteen press releases issued between November 30, 1999 and November 14, 2001 and can be found on the most extensive single-source web-based list of MSF press releases, news bulletins, speeches, and open letters from November 22, 1999 to the present, maintained by MSF-USA, *All content: Access to Medicines*, <http://www.doctorswithoutborders.org/news/allcontent.cfm?id=84> (accessed July 25, 2010).

with which messages were constructed added to the perception of the 'rightness' of MSF's position and their authority within the issue.

The language used by MSF in many of its communications affirmed that states and their agents were the primary actors for resolving the issue. By reinforcing notions of sovereignty and state primacy over the issue, in both setting the rules and being constrained by the rules, states might envision that the TRIPS Agreement undermined their autonomy and conclude that the rules needed to be revised. In addition, moral leverage was used for states that were concerned about their identities in a context of human rights or social justice by drawing attention to the moral obligation to provide for all people, both at home and abroad and may also have helped to persuade governments to reconsider the appropriate balance between health policy and trade interests.

MSF also partnered with international organizations such as the World Bank and WHO to sponsor conferences about identifying and surmounting barriers to medicines and this provided a measure of leverage in persuading states to adopt a different perspective. In addition to educating state officials, MSF became an authoritative resource for future policy discussions.

Another frame that was often utilized reinforced a link between patents and needless deaths. MSF cited its own involvement in these terms: its patients were dying because they lacked lifesaving medicines which are too expensive because of patents. This simplified the issue for a general audience by ignoring the concerns of the pharmaceutical industry, leaving the viewer to interpret the frame and draw conclusions based on prior knowledge and associative understandings of the world. Because corporations were already 'villainized' in the media for social justice issues such as the use of child labour

and environmental degradation,³⁶¹ it was seamless to imagine that drug companies would place corporate greed before human life. This was particularly effective for attracting new members across the globe to the growing movement within civil society that was protesting more generally against the power and policies of transnational corporations, and put sustained pressure on governments ‘from below.’

While MSF used the frame that pointed toward corporate greed for one audience, it also argued that, in general, it was not against the use of patents. In this frame, MSF was targeting drug companies to lower their prices or allow generic manufacturing of their products specifically in poor countries, as well as to recognize states’ legal right to use compulsory licensing and parallel importing within the TRIPS Agreement. As Orbinski noted, the advantage of having a decentralized access network meant that while some members were attacking “unjust policies and practices,” others could be “negotiating specific arrangements with the pharmaceutical industry and pushing governments to meet their responsibilities.”³⁶²

In what could be considered symbolic politics, many of the posters and graphics used in MSF’s promotional materials, travelling poster display and on their website attacked unaffordable drug prices or the lack of research for tropical diseases. These frames were aimed at mobilizing populations living in developed countries where a basic tension exists between publicly provided health care that benefits all and privately accessed care founded on liberal policies. According to Löfgren, welfare state policies fostered “popular expectations for medicines to be available on the basis of need, not ability to

³⁶¹ Examples include the protest movements against Nike and Nestle, resource extraction methods and their dangers (oil spills, clear cutting forests and open pit mining) which were prevalent in the news in the late 1990s.

³⁶² Orbinski, *Imperfect Offering*, 373.

pay”³⁶³ and in spite of the transition to the market-based economy, most wealthy states have retained publicly financed insurance programs to subsidize and ensure access to pharmaceuticals.³⁶⁴

Some of the materials MSF used could garner support from citizens who shared these expectations. Alongside the traditional humanitarian images of sick children and persons with bodies ravaged by tropical diseases,³⁶⁵ were more modern depictions that focused on the cure - which was being withheld - rather than the illness. The graphics were aimed more toward raising awareness of the issue rather than as a plea for financial donations for a specific crisis, and frequently set up a polarized perception of ‘us’ and ‘them.’ Aligned with the beliefs of the MSF founders, the images might serve to evoke an emotive response of anger or indignation that medicines were possible, an injustice was occurring toward the most vulnerable members of society, and individual actions could help make it right. This is consistent with the theory that by framing issues in terms of right and wrong, the message will appeal to those who share similar principles, and individuals might be persuaded to act.³⁶⁶ Examples of these materials include a poster of a pink birthday cake with two lit candles entitled ‘Millions of Babies Won’t Live to See This Day’³⁶⁷ and one created for MSF-Canada that depicts a white pill set as a gemstone in a ring captioned ‘Medicine Shouldn’t Be a Luxury.’³⁶⁸

³⁶³ Löfgren, 254.

³⁶⁴ Ibid., 254-255.

³⁶⁵ For a discussion on the most prevalent imagery used for humanitarian crises, see David Campbell, “Poststructuralism,” in *International Relations Theories: Discipline and Diversity*, ed. Tim Dunne, Milja Kurki and Steve Smith (UK: Oxford University Press, 2007), 220-225.

³⁶⁶ Keck and Sikkink, *Activists beyond Borders*, 19. Olesen, 10-11.

³⁶⁷ This poster was included in an exhibition of MSF posters shown in Guangzhou, China in August 2009 to bring attention to ongoing humanitarian crises, and can be viewed at http://www.lifeofguangzhou.com/node_10/node_35/node_116/node_118/2009/07/24/124842172667713.shtml (accessed July 29, 2010).

³⁶⁸ MSF, “Three years of Access Campaign posters.”

Accountability politics is used to embarrass actors by pointing out the disparity between principles, commitments and actions. The coalition seized on several opportunities to show hypocrisy in state behaviour. An example that may have impacted the Doha Declaration was the coalition's public criticism of Canada and the U.S. for considering compulsory licensing to counter Bayer's prices for ciprofloxacin during the anthrax scare, while routinely opposing the right of developing states to do the same for HIV/AIDS. MSF's publications warning states against entering into free trade agreements with the U.S. and the E.U. due to their "TRIPS-plus" constraints is another example of calling into question commitments made by these states.

The coalition similarly targeted pharmaceutical companies. A key factor in the lowering of anti-retroviral drug prices in 2001 was the announcement that Cipla would supply a year's supply of the generic versions to MSF for \$350 per patient, a huge reduction from Glaxo's \$10,400. MSF continues to publicly expose drug price disparities between countries in its online publication, "Untangling the Web of Antiretroviral Price Reductions."

Theoretical Implications of the Case Study

In the preceding chapters, I have highlighted the progression and key motivating factors behind the inclusion of intellectual property rights in the international trade regime of the World Trade Organization. I have also examined the advocacy role performed by non-state actors, with emphasis on Médecins Sans Frontières, through a campaign that challenged the claims made by pharmaceutical companies and focused on

mechanisms that could allow resource-poor states affordable access to essential medicines and new drugs for tropical diseases.

From the viewpoint of transnational corporations, safeguarding intellectual property rights was crucial for controlling production and maximizing profits. Rapidly evolving technologies and communications systems had a profound effect on knowledge-intensive industries, enabling free-riding manufacturers to erode traditional market shares by offering lower priced copies or by developing similar goods without incurring the financial burden of the initial research, product testing and marketing. As private entities, corporations could be expected to promote a strong IP regime to remain profitable and viable, and to generate resources to re-invest in research and development.

For the more powerful states that directly benefitted from corporate activities, strengthened intellectual property rules were necessary for the retention of trade advantages in a liberalized market-driven economy and for access to the technologies that evolved from research and development. From the perspective of both realism and liberalism, states are rational actors in pursuit of gains, and they will employ a “logic of consequentialism” when strategically bargaining to bring about the best possible outcome.³⁶⁹ For realists, this means that states would be expected to protect their assets to ensure their future security, while liberal theorists would argue that states would respond to domestic pressures from competing constituencies, especially corporations seeking to further their interests. From either perspective, it would be expected that the more powerful states, where the largest pharmaceutical companies were based, would pursue and defend trade rules that served to protect and enhance economic power.

³⁶⁹ Risse, “Let’s Argue”, 2-4.

The logic of consequences was also present in developing and lesser developed states, although they initially resisted the terms of the TRIPS Agreement. Membership in the WTO was based on the total package rather than the piecemeal treaty that plagued the GATT. A cost-benefit analysis gave preference to the gains that could be realized from the promised agricultural and textile markets, transfer of technology, and 'most-favoured nation' status over the concessions required in the TRIPS Agreement. In retrospect however, the substantive effects of "TRIPS" were grossly underestimated.

Standardized patent protection in particular led to serious consequences for accessing pharmaceuticals and was particularly punitive for countries that lacked manufacturing capacity. However, the patent regime was created when new medicines were not expected for the diseases of the south. For example, during the early years of the Uruguay Round, HIV/AIDS treatments did not exist and the virus was not widely understood even in industrialized states. The enforcement of structural adjustment policies that tended to undermine national health programs and other social spending in developing states is evidence of how unconcerned policy makers were about health systems in general, focusing instead on neo-liberal economic principles to foster development.³⁷⁰ Moreover, many governments, particularly in Africa, did not have adequate information collection systems and had not yet acknowledged the extent of the HIV/AIDS crisis nor envisioned the reversing effect it would have on state development.³⁷¹

³⁷⁰ Caroline Khoubessarian, "Global Health Initiatives: A Healthy Governance Response," in *Innovation in Global Health Governance*, ed. Andrew F. Cooper and John J. Kirton (UK: Ashgate Publishing, 2009), 289-290. See also Buckley and Baker, 213-216.

³⁷¹ WHO, "HIV Surveillance Report." The lack of reporting, slow responses and denials by key governments and officials in Africa is well documented by Amy S. Patterson (ed.), *The African State and the AIDS Crisis* (U.K.: Ashgate Publishing, 2005).

As demonstrated in this case study, wealthy states had much to gain from enforcing intellectual property rights. Traditional theories would expect states to protect their material interests therefore the norms of the liberalized market economy should logically take precedence over the protection of social rights. However, after intense negotiations at the WTO, states confirmed the right to use compulsory licensing and parallel importing, adjusted some of the terms of the TRIPS Agreements, and created mechanisms for resource-poor states to use the flexibilities. This behaviour is inconsistent with the expectations of traditional realist and liberal theories.

To understand why states chose to recognize the primacy of health over economic gains, we can turn to a constructivist approach to international relations theory. The constructivist position acknowledges the importance of material concerns, yet argues that state identities are also an important factor in determining their actions. Constructivists assume that state interests and preferences are not deemed to be fixed and are subject to reason in a given situation. Mutually shared values and norms constitute what is considered to be legitimate or desired behaviour and the “logic of appropriateness” can become influential in shaping state interests, determining actions and outcomes.³⁷²

In this case, it appears that wealthy states were influenced by arguments posited by the advocacy coalition based on ideas of what would constitute appropriate or moral behaviour. While the pharmaceutical lobby appealed to state-recognized norms of the liberalized market economy, the advocacy campaign argued for the state-recognized norm of the right to health. In addition, the advocacy coalition insisted that states must be allowed to exercise their sovereign right to provide healthcare for their people, which included measures needed to access essential medicines. By adopting the language of

³⁷² Risse, “Let’s Argue,” 6-7.

both a right to health and the sovereign right to protect health policy, the advocacy campaign was able to appeal to a wide constituency of states and range of interests that constructivists argue can be subject to change.

Conceding that human rights should take precedence over purely economic objectives is also consistent with the constructivist claim that states are concerned with signaling their identity as a member of the community of liberal states. Theorists suggest that states and state leaders are concerned about reputation, want to belong, and will usually try to do the 'right' thing.³⁷³ In addition, the medicines issue gained salience in that it sought primarily to protect vulnerable populations and prevent needless suffering and premature deaths.³⁷⁴

A shift in state behaviour usually requires a transition between competing normative frameworks in belief and practice and may require an institutional response to clarify the new norm and its parameters.³⁷⁵ In this case, the coalition targeted not only states and corporations, but also the international organization that oversees trade. Therefore the institutional response is entrenched in the Doha Declaration and revised TRIPS Agreement which provide the primary rules for protecting drug patents, as well as the procedures for enforcement and adjudication of disputes. Meanwhile, the main treaty that enumerates the right to health is the International Covenant on the Economic, Social and Cultural Rights. The arguments presented by the access campaign also benefitted by their alignment with the Millennium Goals that reinforce social rights.

For the most part, the constructivist approach seems to provide a more inclusive explanation for why states in this case were willing to adopt new policies. However, the

³⁷³ Finnemore and Sikkink, "International Norm Dynamics," 902-904.

³⁷⁴ Keck and Sikkink, *Activists beyond Borders*, 27.

³⁷⁵ Finnemore and Sikkink, "International Norm Dynamics," 900.

United States remains somewhat of an outlier. While the U.S. eventually conceded to a revision in the TRIPS Agreement, it continued to put pressure on many states that tried to use the legal provisions of compulsory licensing and parallel importing through the threat or use of its Section 301 powers. In addition, the U.S. has continued to negotiate free trade agreements with several states, including some within the developing world, that include provisions that exceed the intellectual property provisions contained within the TRIPS Agreement. The explanation for this may include several factors.

First, the U.S. had more to lose than other states in a weakened IP regime because the majority of large pharmaceutical corporations and knowledge intensive industries were US-based so the economic and technological benefits to the state were considerable. By entering into external free trade agreements that reflect more stringent standards, the U.S. could continue to protect its economic interests and signal to the corporate community that it is 'business as usual.' Second, negotiators for the U.S. were hesitant to concede to demands that would set a precedent or offer an interpretation that could be extended to other areas of trade law and negotiations. By entering into separate free trade agreements, the U.S. could tighten its control and enforcement powers over specific areas of trade such as pharmaceuticals on a case by case basis. Third, the U.S. found an alternative method to signal its commitment to the international community using means other than trade concessions by entering into global funding arrangements to provide medicines for low income states and to assist with incentives for research and development. Fourth, in response to domestic pressures, the U.S. also initiated its own PEPFAR program and funds a large number of U.S.-based development and faith-based organizations active in providing treatment and education for HIV/AIDS. This allows the state to maintain

accountability and control over the types of programs it will fund and importantly over the decision of who will benefit, which may provide incentives for poor countries to cooperate with U.S. demands in other areas. Finally, the asymmetrical power structure between the U.S. and most other states continues to influence the strength of bargaining positions in trade agreements and frequently results in states accepting constraints insisted upon by the U.S. in some areas in order to gain the advantages offered in other areas.

Although this paper is limited to one case study, there are some generalizations that can be forwarded. First, this case provides evidence that states are open to policy considerations and collective international arrangements that recognize normative understandings of human rights as prior to, or equal to the norms that underpin material and economic gain. This is not consistent with traditional theories that place security issues and material concerns as the primary drivers of state behaviour, and suggests that other theoretical concepts are necessary for understanding contemporary state relations. For example, the constructivist view that state identities and interests are formed and subject to change as the result of ideational factors seems persuasive in this case.

There is also evidence that the recognition of human rights as a factor in international agreements is not limited to civil and political rights, but now may extend to important social rights. This theme was recently adopted by the WTO Director-General Pascal Lamy in a speech that claimed that “trade and human rights go hand in hand,”³⁷⁶ and he drew not only on the example of access to medicines, but also linked the negotiations concerning agriculture to the right to food. This suggests that in future states may be

³⁷⁶ WTO, “WTO News: Speeches – DG Pascal Lamy, Trade and Human Rights Go Hand in Hand,” speech to UNITAR, September 26, 2010, http://www.wto.org/english/news_e/sppl_e/sppl172_e.htm/ (accessed October 3, 2010).

expected to consider the externalities created by liberal trade policies and incorporate concrete solutions to minimize negative impacts, particularly in poor countries.

It is also apparent that non-state actors have a significant role to play in identifying issues that affect the set of rights contained in the ICESCR. What is unusual is that this will frequently require advocacy that is aligned with the interests of governments in the developing world, and may not garner much initial support from more powerful states. This is a departure from most prior human rights issues that featured advocacy of civil and political rights, and generally targeted oppressive policies in developing states. On the international level, this may require a more concerted effort between domestic non-governmental organizations, affected governments, international organizations and transnational advocacy groups.

The depth and breadth of collaboration that may be required is evident in the access campaign. Its success relied heavily on the grassroots participation of TAC in South Africa and domestic groups like ACT UP and CP Tech in the US that directly confronted their governments' policies. In addition, the demands of the African states and Brazil at the WTO were instrumental in bringing the TRIPS Agreement back to the negotiating table. Some of this participation was possible due to the educational component of the campaign and the resources made available by international organizations such as WHO and World Bank in conjunction with the transnational coalition that had first identified and launched the access campaign, including HAI, Oxfam and MSF.

Further Research for Pharmaceutical Access and Health

It is estimated that about a third of the world, and up to 50% in Africa, still do not have access to essential medicines. While some might consider this a campaign and policy failure, drug access is improving steadily and there is evidence that investment in research for neglected diseases has increased. However, donor fatigue has been noted in decreasing global financing, and it has been stressed that states must be proactive in using the flexibilities in the TRIPS Agreement and in improving domestic infrastructure and health delivery systems. Accordingly, the WTO periodically sponsors seminars on the use of the TRIPS Agreement, but further research is needed to determine what barriers still exist in the area of access. Barriers might include the complexities in exporting medicines under compulsory license as experienced by the Canadian generic manufacturer Apotex, or may potentially be linked to provisions in other free trade agreements, such as those with the U.S.

MSF and other members of the access coalition have continued to monitor drug prices, free trade agreements, and research for new treatments, but concern has arisen that the newer drug formulas for diseases are again not reaching poor countries. In response, MSF has added to its campaign a medical innovation section that is in support of a new global framework based on need rather than the market.³⁷⁷ Another addition to their formal campaign is malnutrition because it has been identified as a key contributor to premature death from other diseases.³⁷⁸ However, while the network may remain active through multiple linkages, the access coalition appears to have disbanded. This could

³⁷⁷ MSF, "Medical Innovation," <http://www.msfaccess.org/main/medical-innovation/> (accessed July 26, 2010).

³⁷⁸ MSF, "MSF and Malnutrition," <http://www.msfaccess.org/main/malnutrition/introduction-to-malnutrition/msf-and-malnutrition/> (accessed July 26, 2010).

provide another area of future research to consider the impact that is possible without the support of a wide-reaching coalition. In particular, will MSF be able to make substantial progress in the newer issue-areas and if so, what resources are required to be successful?

Recently, the World Bank and WHO have invested resources into understanding how health is related to development and the social determinants of health have evolved to include a vast range of social factors beyond food, water, housing and medicines. Determinants, which are intrinsically linked to poverty, are now understood to include such issues as gender equality, education, environmental degradation and labour conditions. It is widely acknowledged that the duty to coordinate services, treat disease and illness, and monitor outcomes goes beyond the capacity of the state and involves multiple levels of stakeholders. Sustainable health plans require the participation of states, corporations, international organizations, NGOs, private donors and foundations, communities and individuals.³⁷⁹

This collaboration of state and non-state actors is consistent with Ruggie's conception of the new global public domain where the governance of certain issues that transcend state borders becomes the shared responsibility of a variety of social actors. Further research will be needed to determine what constitutes a public good and what role advocacy groups will play in the issues that fall within this domain of global governance.

³⁷⁹ World Health Organization, "Human Rights, Health and Poverty Reduction Strategies," 14.

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